UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, and the States of CALIFORNIA, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA and WISCONSIN, and THE DISTRICT OF COLUMBIA ex rel., Relator, Plaintiff, v. Defendant.	No. 05-12040-RWZ Consolidated Under: Civil Action No. 04-11780-DPW **AMENDED COMPLAINT AND JURY DEMAND** Filed Under Seal pursuant to 31 U.S.C. § 3730 (b)(2) JURY TRIAL DEMANDED

Michael T. Anderson, Esq.
BBO # 645533
MURPHY ANDERSON, PLLC
111 Devonshire St. 5th Fl.
Boston, MA 02109
Phone: (617) 227-5720
Fax: (617) 227-5767
manderson@murphypllc.com

Mark Hanna, Esq.
MURPHY ANDERSON PLLC
1701 K Street, NW, Suite 210
Washington, DC 20006
Phone: (202) 223-1057
Fax: (202) 223-8651
mhanna@murphypllc.com

Ann Lugbill, Esq. (Ohio Bar 0023632)
MURPHY ANDERSON, PLLC
2406 Auburn Avenue
Cincinnati, OH 45219
Phone: (513) 784-1280
Fax: (513) 784-1449
alugbill@murphypllc.com

John Kairis, Esq.
GRANT & EISENHOFER, PA
Chase Manhattan Centre
1201 North Market Street
Wilmington, DE 19801
Phone: (302) 622-7000
Fax: (302) 622-7100
jkairis@gelaw.com

Reuben Guttman, Esq.
Traci Buschner, Esq.
GRANT & EISENHOFER, PA
1920 L Street, NW, Suite 400
Washington, DC 20036
Phone: (202) 386-9500
Fax: (202) 386-9505
rguttman@gelaw.com
tbuschner@gelaw.com

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Fax: (617) 227-5767
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I. INTRODUCTION

1. Qui Tam Relator Glenn DeMott brings this action in the name of the United States Government and the State Governments of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Mexico, New York, New Jersey, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin and the District of Columbia ("States"), for false claims that were submitted or caused to be submitted to the United States Government and the States by Defendant Pfizer, Inc., including Pharmacia, Inc. and other predecessor companies.

2. This case is brought pursuant to the qui tam provisions of the Federal False Claims Act, 31 U.S.C. § 3729 *et seq*., and pursuant to analogous provisions of state law, to recover treble damages and civil penalties on behalf of the United States of America and the States, arising from false or fraudulent claims for reimbursements for prescription drugs that were submitted or caused to be submitted by Pfizer to federal government-funded programs including, without limitation, Medicaid, Medicare, the Federal Employees Health Benefits Program, and TRICARE/CHAMPUS, in violation of the False Claims Act. The False Claims Act specifically proscribes Pfizer's conduct involving unlawful marketing of prescription drugs, illegal kickbacks, and thus the submission of false or non-reimbursable claims to Medicaid and other government-funded health programs. The drugs encompassed by this complaint include Celebrex, Bextra, Lyrica, Relpax, Depo-Provera, and Geodon.

3. Relator Glenn DeMott, a former Pfizer senior sales representative and sales consultant, was terminated from his job after he investigated and documented Pfizer's False Claims

Act violations, including violations of its existing Corporate Integrity Agreement with the United States Department of Health and Human Services as further alleged herein.

4. Defendant's False Claims Act violations and its various marketing schemes corrupted the independent medical judgment of physicians, unlawfully increased costs to the United States for prescription drugs, and risked patients' health by improperly influencing physicians' decisions about whether to prescribe drugs and included:

a. Pfizer's off-label and other illegal marketing activities in violation of the False Claims Act and federal United States Food and Drug Administration (FDA) laws and regulations by:

i. Misrepresenting published research data;

ii. Engaging in prohibited dissemination and sales promotion ("detailing") of off-label studies;

iii. Fabricating requests for information from Pfizer's Medical and Drug information unit regarding comparative safety in order to send off-label marketing materials to physicians;

iv. Utilizing physician speakers for off-label promotion and to influence off-label prescribing;

v. Misbranding drugs by placing samples in plastic bags to distribute as samples, without package inserts;

vi. Falsely making and promoting claims of superior efficacy and safety; and

vii. Assisting physicians in obtaining Medicaid prior authorization for prescriptions.

b. Pfizer's off-label and illegal marketing of its drug Bextra, approved by the FDA only for treatment of rheumatoid arthritis, osteoarthritis, and menstrual pain, by unlawfully claiming that Bextra provided, among other things:

i. Acute pain relief for dental, podiatric, orthopedic and pre and post-operative pain uses;

ii. Superior efficacy to Vioxx and traditional NSAIDS (non-steroidal anti-inflammatory drugs); and

iii. rapid and powerful relief in 26 minutes.

c. Pfizer's off-label and unlawful marketing of Celebrex, including aggressive promotion that it provided superior gastrointestinal safety and cardiovascular safety, while representing to the FDA it was not making these claims, which led Pfizer to:

i. Misrepresent the Celebrex Long-Term Arthritis Safety Study ("Class Study") to its sales force and directly to physicians;

ii. Falsify and misrepresent comparative efficacy studies to show superior efficacy when the studies showed the opposite; and

iii. Repeatedly misuse scientific materials for physicians from Pfizer's Medical and Drug Information unit to promote Celebrex's safety for patients having cardiovascular conditions.

d. Pfizer's illegal marketing of Relpax, indicated for migraines, by:

i. Implementing an unlawful kickback scheme to pay physicians $250 each, ostensibly to explain Relpax drug information to individual Pfizer sales representatives, but which was in reality a thinly-disguised superficial effort at education designed to facilitate illegal payments to physicians to convince them to prescribe Relpax;

ii. Using reprints of scientific studies with questionable scientific validity to falsely claim superior efficacy to Imitrex, even though FDA investigators had found the studies to be inadequate to make such claims;

iii. Providing gifts to patients in return for filling prescriptions that were paid for by Medicaid, Medicare, and other state and federal government payers;

iv. Employing unscientific "studies" in individual physician offices to increase Relpax use;

v. Paying physicians to individually contact patients by letter and assisting in that process in order to convince patients to switch from other comparably-effective drugs to Relpax; and

vi. Disseminating reprints of off-label study articles not in compliance with FDA regulations.

e. Pfizer's marketing of Lyrica by its sales force before Lyrica's approval by the FDA, promoting off-label uses, such as pain management, and utilizing unqualified paid speakers as a reward for their high Lyrica prescription volume or potential for such high volumes, paid for by Medicaid;

f. Pfizer's dispensing large numbers of Depo-Provera samples to providers in exchange for purchases of additional Depo-Provera and/or other drugs, violating Medicaid "best price" requirements and Pfizer's existing Corporate Integrity Agreement, including by:

i. Pfizer violating laws involving diversion of drugs marked for sample use only; and

ii. Pfizer negotiating "special deals" with some states, but not others, in violation of "best pricing" conditions in supply contracts.

g. Pfizer's unlawful marketing and sales of the psychiatric drug Geodon, including paying kickbacks and ongoing promotion of the drug, even after Pfizer was alerted to the fraudulent nature of the prescriptions and risks to patient safety.

5. Defendant knew or should have known that its unlawful activities would cause physicians and other healthcare professionals to routinely file false claims for reimbursement from the Federal and State governments in violation of the False Claims Act, and involved violations of the Food, Drug and Cosmetics Act, 21 U.S.C. § 301 *et seq*., the Food and Drug Administration and Modernization Act of 1997, 21 U.S.C. § 351 *et seq*. and 21 U.S.C. § 360aaa *et seq*., the Medicare/Medicaid Fraud & Abuse Anti-Kickback Statute, 42 U.S.C. § 1320a *et seq*., the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8, and similar State laws.

6. Because of Pfizer's unlawful promotion scheme, patients receiving Pfizer prescription drugs for unapproved and unproven uses received no assurance that their doctors were exercising their independent and fully-informed medical judgment.

7. Defendant's scheme illegally increased the market share for its products by inducing physicians to prescribe medications they would not otherwise have prescribed but for the receipt of the kickbacks and/or other illegal marketing efforts. The Federal and State governments consequently paid enormous sums for reimbursement claims they would have rejected had each been aware of Pfizer's illegal actions. Moreover, as a result of Pfizer's illegal promotions, the public over-utilized Pfizer drugs and prescription drug costs to the Federal and State governments soared, while Pfizer reaped illegal profits.

8. Pfizer chose to promote off-label uses of its drugs, despite Pfizer's awareness of the FDA's prohibition of off-label marketing. Pfizer's fraudulent marketing scheme involved promoting unproven claims of superior speed of onset, efficacy, gastrointestinal safety and cardiac safety, and urging higher dosing than was FDA-approved. Pfizer misrepresented scientific research, misused the physician-initiated Pfizer Medical and Drug Information request system, and used unreliable, misleading and irrelevant data to advance claims of superior efficacy and safety.

9. Relator has direct and independent personal knowledge of the Defendant's practices with regard to Bextra, Celebrex, Lyrica, Relpax, Depo-Provera and Geodon as a result of an extensive independent investigation he personally conducted into Pfizer's wrongdoing. Relator brings this action on behalf of himself, the United States of America, and the States for violations of the United States' and States' False Claims Acts.

BEXTRA

10. Pfizer waged an illegal "off-label" marketing campaign to promote the prescription drug Bextra for non-FDA approved uses. The FDA approved Bextra for treatment of rheumatoid arthritis, osteoarthritis, and primary dysmenorrhea (a type of menstrual pain). Rather than awaiting FDA approval for the drug's alternate uses, Pfizer chose to promote such off-label uses of Bextra as providing acute, dental, podiatric, pre-operative and post-operative pain relief, despite Pfizer's awareness of the FDA's prohibition on off-label marketing. Pfizer's fraudulent marketing scheme also involved promotion of unproven claims of superior speed of onset, superior efficacy and superior gastrointestinal safety. To do so, Pfizer misrepresented and falsified data from research studies, made false certifications of physician Medical and Drug Information requests, and used unreliable, misleading and irrelevant data to promote its claims of superior efficacy and cardiovascular and gastrointestinal safety and urge higher dosing than the FDA approved.

CELEBREX

11. Pfizer actively promoted Celebrex, its COX-2 inhibitor, "off-label" to increase its sales of that drug. Celecoxib is a non-steroidal anti-inflammatory COX-2 inhibitor manufactured and marketed by Pfizer under the brand name "Celebrex." The FDA approved Celebrex on December 31, 1998 for the treatment of pain and inflammation associated with adult rheumatoid arthritis and osteoarthritis. The FDA expanded Celebrex's approved uses after the initial approval, but never generally expanded it for all types of pain or inflammation. Additional later approvals were for Familial Adenomatous Polyposis (FAP); for management and treatment of primary dysmenorrhea (a type of menstrual

pain); for juvenile rheumatoid arthritis; for ankylosing spondylitis; and for acute pain in adults arising from dental or orthopedic surgery.

12. Pfizer promoted Celebrex as having superior efficacy, superior gastrointestinal safety, and superior cardiovascular and cardio-renal safety. These false claims of Celebrex's properties diminished the safety warning sections of the package insert and caused physicians to expand their use of Celebrex to patients who would not otherwise have received the drug because of the patient's risk factors.

LYRICA

13. Pfizer sales representatives marketed Lyrica for off-label uses, including for pain, in advance of its approval by the FDA and thereafter. Pfizer's agents falsified physician requests for medical information concerning Pfizer's prescription drug Lyrica before that drug had been approved for any uses by the FDA. When Relator reported this conduct to Pfizer's Compliance Department, Pfizer took no action against the sales representatives, in violation of the terms of its Corporate Integrity Agreement.

RELPAX

14. Pfizer routinely paid improper kickbacks to physicians in order to induce those physicians to prescribe Pfizer's migraine prescription drug Relpax and engaged in other unlawful marketing practices to increase Relpax sales. These kickback schemes violated 42 U.S.C. § 1320a-7b(b) (the "Medicare Fraud & Abuse/Anti-Kickback Statute") and caused false or fraudulent claims for Pfizer's drugs to be filed by physicians and medical institutions for reimbursement from Federal and State government-funded health programs. Pfizer misrepresented the results of scientific studies to promote Relpax over competitors'

migraine medication and illegally used information from the studies to promote Relpax, including promoting dosages that were higher than the FDA had approved.

DEPO-PROVERA

15. For years, Pharmacia, Pfizer's predecessor, trained and encouraged its district managers and sales representatives to "do deals" and "barter" with physicians and medical institutions by offering large quantities of drug samples (what Pfizer now calls "starters") in exchange for large or standing orders from the physicians and medical institutions for those or other drugs. This became an accepted practice that later resulted in Pfizer-trained District Managers and sales representatives exchanging large numbers of Pfizer-supplied Depo-Provera (an injectable contraceptive) samples (up to 100) in return for the physicians and medical institutions placing larger Depo-Provera orders. To accomplish this, Pfizer sales representatives first promised physicians free sample doses of Depo-Provera, an injectable contraceptive, in exchange for the physicians purchasing Estring (FDA approved for treating various post-menopausal conditions). This bartering continued thereafter, without Estring, which illegally manipulated Medicaid "best price" and "average manufacturer price" reimbursement and rebate calculations. The deals drastically decreased the average wholesale price per dose paid and reimbursed the physicians at an artificially higher rate. This practice also improperly influenced physicians' decisions about whether to prescribe Depo-Provera, so that patients receiving those drugs could not be certain that their treatment was guided solely by their physicians' independent medical assessment of their diagnoses.

GEODON

16. Pfizer marketed its atypical antipsychotic drug, Geodon (ziprasidone hydrochloride), initially indicated for the treatment of schizophrenia, to a high-volume Medicaid clinic called Townstreet Medical Clinic, located in Columbus, Ohio. Pfizer aggressively promoted Geodon to this practice, which served a large Medicaid patient population, despite the fact that Pfizer was aware of a dangerous side effect caused by the drug. In particular, Geodon could create serious, potentially fatal heartbeat irregularities. Pfizer engaged in a pattern of reckless marketing of Geodon, while knowing that Geodon was being used off-label for conditions other than its approved uses. In addition to this aggressive marketing for non-indicated purposes, Pfizer paid kickbacks to the Townstreet Clinic through the payment of grants and "preceptorships." Defendant continued to aggressively market to the Townstreet Clinic physicians even after the prescriptions were known to be inappropriate and fraudulent.

II. JURISDICTION AND VENUE

17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a), which specifically confers jurisdiction to this Court over actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. This Court also has subject matter jurisdiction over the counts relating to the State False Claims Acts pursuant to 31 U.S.C. § 3732(b), as well as supplemental jurisdiction over the counts relating to the state false claims acts pursuant to 28 U.S.C. § 1367.

18. This Court has personal jurisdiction over the Defendant pursuant to 31 U.S.C. § 3732(a) because acts prohibited by 31 U.S.C. § 3729 occurred in this state and this judicial

district. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because at least one act proscribed by 31 U.S.C. § 3729 occurred in this district.

19. In accordance with 31 U.S.C. § 3730(b)(2), the original Complaint was filed under seal and this Amended Complaint is likewise filed under seal and will remain under seal for a period of at least 60 days from its filing date or such other date as the Court so orders, and shall not be served upon the Defendant unless the Court so orders.

20. This suit is not based upon prior public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit or investigation, in a Government Accountability Office or Auditor General's report, hearing, audit, or investigation, from the news media, or in any other location as the term "publicly disclosed" is defined in 31 U.S.C. § 3730 (e)(4)(A). Relator has, however, affirmatively disclosed the allegations herein to the United States FDA, the States, and the United States Department of Justice, including prior to filing his case and/or his amendments to the Complaint.

21. To the extent that there has been a public disclosure of the information upon which the allegations of this Complaint are based that is unknown to Relator, Relator is an original source of this information as defined in 31 U.S.C. § 3730(e)(4)(B) and similar state law provisions. Relator possesses direct and independent knowledge of the information, which he acquired in the course of his Pfizer employment, and thereafter, as a result of his investigation. Relator voluntarily provided the government with this information prior to filing this action. See 31 U.S.C. § 3730(e)(4).

III. PARTIES

A. Relator Glenn DeMott

22. Relator Glenn DeMott resides in Columbus, Ohio, where he was employed by Upjohn as a sales representative from 1987 to 1996. When Upjohn merged with Pharmacia Corp. in 1996, Mr. DeMott was promoted to Pharmaceutical Sales Senior Consultant. He continued in that position after Pfizer purchased Pharmacia in April 2003. Mr. DeMott has 19 years experience in pharmaceutical sales.

23. Throughout his career, Mr. DeMott earned numerous regional and national sales awards, including the Pharmacia CEO's Champion Award in 2000 and sales rankings of #1 in the Great Lakes Region for sales of Celebrex in 2000 and COX-2 inhibitor drugs (Celebrex and Bextra) in 2002. Mr. DeMott also underwent extensive sales and compliance training while at Upjohn and Pharmacia and his experience afforded him a special familiarity with FDA regulations and compliance issues that made him especially alert to Pharmacia's and Pfizer's persistent violations of those regulations.

24. As a Pharmaceutical Sales Senior Consultant with Pfizer, Mr. DeMott engaged in sales and advised sales representatives on building relationships with current and potential clients. Each time Mr. DeMott learned of marketing or promotion efforts that did not comply with company policy or FDA regulations, he reported the activity first to his District Managers and then directly to Pfizer's Compliance Department, as set forth in Pfizer's established Disclosure Program.

25. Notwithstanding Pfizer's obligations under the False Claims Act and Pfizer's own Corporate Integrity Agreement to provide a non-retaliatory and harassment-free environment for employees reporting compliance violations, Pfizer placed Mr. DeMott on

administrative leave immediately after, and in retaliation for, following company policy and reporting compliance violations through the Pfizer Disclosure Program. Pfizer placed Mr. DeMott on administrative leave on November 2, 2004 and subsequently terminated his employment after 19 years with Pfizer and its predecessors on April 15, 2005.

B. Defendant Pfizer

26. Defendant Pfizer is a Delaware corporation with its principal place of business in New York, New York. Pfizer is engaged in the business of manufacturing, marketing, and selling prescription drugs and other products for the prevention, diagnosis, and treatment of diseases throughout the United States of America and around the world. Among its many products, Pfizer manufactures and markets the prescription drugs Bextra, Celebrex, Lyrica, Relpax, Depo-Provera, and Geodon. Pfizer generated revenues of approximately $52.5 billion in the U.S. for the fiscal year ending December 31, 2004.

IV. REGULATORY FRAMEWORK

A. Federal and State Government Health Programs

27. The Federal and State governments, through their Medicaid and Medicare programs, are among the principal purchasers of Pfizer products.

28. Medicare is a federal government health program primarily benefitting the elderly created by Congress in 1965 when it adopted Title XVIII of the Social Security Act. Medicare is administered by the Centers for Medicare and Medicaid Services ("CMS"). Medicare would not pay for over-the-counter drugs or for most self-administered prescription drugs until the Medicare Prescription Drug Improvement and Modernization Act of 2003 was fully implemented. Under certain conditions, however, Medicare Part B covers self-administered prescription drugs.

29. Congress created Medicaid at the same time it created Medicare in 1965 when Title XIX was added to the Social Security Act. Medicaid is a public assistance program that provides payment of medical expenses to low-income patients. Funding for Medicaid is shared between the Federal government and those State governments choosing to participate in the program. The Federal government also separately matches certain State expenses incurred in administering the Medicaid program. While specific State Medicaid coverage guidelines vary, Medicaid's coverage is generally modeled after Medicare's coverage.

30. Until the Medicare Prescription Drug Improvement and Modernization Act, Medicaid coverage for prescription drugs was significantly more expansive than that provided by Medicare. Nearly every state has opted to include basic prescription drug coverage in its Medicaid plan.

31. TRICARE is the health care system of the United States military, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents. The program operates through various military-operated hospitals and clinics worldwide and is supplemented through contracts with civilian health care providers. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations and fee-for-service benefits. Five managed care support contractors create networks of civilian health care providers. Military prescription drug benefits are provided through three programs: military treatment facility outpatient

pharmacies, TRICARE contractor retail pharmacies, and a national contractor's mail-order service.

32. The Federal Employees Health Benefits Program ("FEHBP") provides health insurance coverage for about 8 million federal employees, retirees, and their dependents. FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association, and Rural Carrier Benefit Plan. FEHBP plans are managed by the Office of Personnel Management.

B. The False Claims Act

33. Originally enacted in 1863, the False Claims Act was substantially amended in 1986 by the False Claims Amendments Act. The 1986 amendments enhanced the Government's ability to recover losses sustained as a result of fraud against the United States.

34. The False Claims Act provides that any person who knowingly presents or causes another to present a false or fraudulent claim to the Government for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. 31 U.S.C. § 3729(a)(1),(2). The False Claims Act empowers private persons who have information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery. The complaint must be filed under seal without service on any defendant. The complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to join the action.

35. Knowingly paying kickbacks or undisclosed price discounts to physicians to induce them to prescribe a reimbursable drug, and promoting off-label uses of such drugs by a person who seeks reimbursement from a federal government health program for the drug, or who

causes another to do so, while certifying compliance with the Medicare Fraud & Abuse/Anti-Kickback Statute, the Medicaid Rebate Statute, and the Food, Drug and Cosmetics Act (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates the False Claims Act.

C. FDA Regulation of Drug Marketing and Advertising

36. The FDA regulates drugs based on the "intended uses" for such products. A manufacturer that wishes to market any new drug must demonstrate to the FDA that the product is safe and effective for each intended use. 21 U.S.C. § 331(d); 21 U.S.C. §§ 355(a), 360b(a).

37. The Food and Drug Act requires that all "new drugs," 21 U.S.C. § 321(p), be approved by the FDA as safe and effective prior to marketing. The marketing of a new drug without pre-approval from the FDA violates 21 U.S.C. §§ 355 and 331(d), of the Food, Drug and Cosmetics Act.

38. The FDA reviews a pharmaceutical manufacturer's application for approval of a new drug to determine whether the drug's intended use is safe and effective. 21 U.S.C. § 355. "Off-label" refers to the marketing of an FDA-approved drug for uses that have not undergone FDA scrutiny and approval, i.e., for purposes not approved by the FDA.

39. Once a drug is approved for a particular use, the FDA allows doctors to prescribe the drug for medical uses that are different from those approved by the FDA. The FDA also allows doctors to request information from drug manufacturers about off-label uses of FDA-approved drugs. However, with very few exceptions, the FDA prohibits drug manufacturers from marketing, advertising, or promoting a drug for a use that the FDA has not yet approved.

40. Each State Medicaid program has the power to exclude any drug from coverage if the prescription is not issued for a "medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B). A "medically accepted indication" includes only those indications approved by the FDA and those "off-label" uses that are supported by one or more citations included in one of the drug compendia listed in 42 U.S.C. § 1396r-8(k)(6).

41. Pursuant to the Food, Drug and Cosmetics Act (FDCA), 21 U.S.C. §§ 301, *et seq*., the FDA strictly regulates, among other things, the content of direct-to-physician product promotion and drug labeling information used by pharmaceutical companies in promoting and selling FDA-approved prescription drugs.

42. Any failure to fairly and accurately represent the approved uses, safety and other required information about a prescription drug is considered misbranding and is, as a matter of law, a false and fraudulent statement. 21 U.S.C. §§ 331(a)-(b), 352(a),(f),(n).

43. Any presentations, promotions, or marketing to physicians of products for use in a manner other than that approved for labeling purposes by the FDA is considered off-label marketing and is proscribed by the FDA. 21 U.S.C. §§ 331(a)-(b), 352(a),(f).

44. FDA regulations, summarized in Pfizer's corporate "Key Principles Guide to Health Law Compliance," prohibit pharmaceutical companies from actively discussing or detailing off-label uses of drugs in a promotional manner and/or misrepresenting product qualities. If a physician makes an unsolicited request for information about an off-label use of a drug, a sales representative is permitted to respond by requesting information from Pfizer's Medical and Drug Information unit and/or delivering to the physician's office any articles or studies that address the physician's inquiry and are approved by Pfizer's pharmaceutical Product Review Committee and filed with the FDA. FDA regulations,

however, prohibit representatives from discussing or detailing studies of off-label uses under any circumstance.

45. Verbal use of Pfizer Medical Drug Information was a prohibited practice because the Food, Drug, & Cosmetics Act, 21 U.S.C. § 360aaa *et seq*., required that the off-label promotion only be disseminated to doctors in writing, that the written materials meet applicable scientific criteria, and that the materials be properly disclosed in advance to the FDA.

46. The United States and the States would not have issued reimbursements for off-label sales of Bextra, Celebrex, Relpax, Lyrica, Depo-Provera, and Geodon had they known the truth about Pfizer's illegal marketing scheme. Every reimbursement sought from Medicaid, Medicare, and other government health care programs for such purchases or prescriptions as a result of Pfizer's aggressive off-label marketing constitutes a false claim under the False Claims Act.

47. The FDA prohibits manufacturers from making claims in drug marketing materials that the FDA previously reviewed and were not included in the package insert. Thus, Pfizer's marketing scheme utilizing such claims is prohibited by FDA marketing and advertising statutes and regulations. *See,* 21 C.F.R. § 202.1.

D. The Medicare Fraud & Abuse/Anti-Kickback Statute

48. The Medicare Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), which also covers Medicaid, provides penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce the referral of business reimbursable under a federal health benefits program. The offense is a felony punishable by a fine of up to $25,000 and imprisonment for up to 5 years.

49. In accordance with the Anti-Kickback Statute, Medicare regulations directly prohibit any provider from receiving remuneration paid with the intent to induce referrals or business orders, including the prescription of pharmaceuticals, or from receiving remuneration that takes into account the volume or value of any referrals or business generated. 42 C.F.R. § 1001.952(f). Remuneration paid to providers is an illegal kickback when it is paid to induce or reward the drug prescriptions written by physicians. Kickbacks are harmful to public policy because they increase the expenditures paid by government-funded health benefit programs by inducing medically unnecessary use of prescription drugs and excessive reimbursements. Such kickbacks also reduce a patient's healthcare choices as unscrupulous or unknowing physicians steer their patients to various drug products based on the physician's own financial interests rather than the patient's medical needs.

50. The Medicare Anti-Kickback Statute provides eight statutory exceptions from its statutory prohibitions, and certain regulatory "safe harbors" have been promulgated to exclude certain types of conduct from the reach of the statute. 42 U.S.C. § 1320a-7(b)(3). None of the available statutory exceptions or regulatory safe harbors protect the Defendant's conduct in this case.

51. The Medicare and Medicaid Patient and Program Protection Act of 1987 authorizes the exclusion of any individual or entity from participation in the Medicare and Medicaid programs if it is determined that the party violated the Medicare Anti-Kickback Statute. In addition, the Balanced Budget Act of 1997 amended the Act to include administrative civil penalties of $50,000 for each act violating the Anti-Kickback Statute, as well as an assessment of not more than three times the amount of remuneration offered, paid,

solicited, or received, without regard to whether a portion of that amount was offered, paid, or received for a lawful purpose. 42 U.S.C. § 1320a-7a(a)(7).

52. As detailed below, Pfizer's pharmaceutical marketing repeatedly violated provisions of the Anti-Kickback Statute and the False Claims Act because Pfizer's improper kickbacks and incentives induced physicians to prescribe Pfizer drugs when they otherwise would not have and many of those prescriptions were paid for by Medicaid and other government funded health insurance programs.

E. The Medicaid Rebate Statute

53. The Medicaid Rebate Statute, 42 U.S.C. § 1396r-8, is designed to return money to the Medicaid program in the form of rebates from drug manufacturers. Federal law provides that drug manufacturers must pay rebates to the states to ensure that the Medicaid program is paying the lowest price at which the manufacturer sells a covered outpatient drug to any purchaser in the United States, inclusive of cash discounts, free goods, kickbacks, volume discounts, and rebates. The "best price" provision is intended to ensure that the government is being provided the lowest price on drugs.

54. To have their drugs eligible for Medicaid payment, all drug manufacturers must provide "best price" information to the Centers for Medicare and Medicaid Services ("CMS"). CMS uses this "best price" information to calculate rebates payable to the Medicaid program.

55. Drug manufacturers provide both "best price" information and Average Manufacturer Price information to CMS. CMS then calculates a unit rebate amount and provides that information to State Medicaid agencies. The States then consider utilization data provided by pharmacies, and the unit rebate amount, to calculate the rebate owed to them

by the manufacturer. The entire system, however, relies upon manufacturers honestly conveying to CMS correct "best price" information and Average Manufacturer Price information. Any overstatement of the best price, whether intentional or unintentional, will cause an underpayment in rebate amounts.

56. The Medicaid Rebate Statute states, in part, that the term "best price" shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section). 42 U.S.C. § 1396r-8(c)(1)(c)(ii).

57. The Federal government has great financial interest in the program. The Medicaid Rebate Statute provides that amounts received by the States under the "best prices program" shall be considered to be a reduction in the amount expended under the State Medicaid Plan for purposes of calculating the federal contribution to state Medicaid programs. 42 U.S.C. § 1396r-8(b)(1)(B).

58. As a result of pervasive "best price" fraud, the Office of the Inspector General of the United States Department of Health and Human Services promulgated compliance materials on May 5, 2003, which observed that manufacturers have "a strong financial incentive to hide de facto pricing concessions" (in particular, kickbacks and price discounts) that could affect "best price" calculations and trigger increased Medicaid rebates. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 FEDERAL REGISTER 23731, 23735 (May 5, 2003). The Office of the Inspector General instructed manufacturers to report "best prices" which "accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other

price concessions or similar benefits offered to some or all purchasers." Id. at 23733-23734. According to the Office of the Inspector General, "pharmaceutical manufacturers are responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes." Id.

59. The Medicaid program reimburses doctors only for "covered outpatient drugs" for which a rebate is paid by the drug's manufacturer. 42 U.S.C. § 1396b(i)(10).

F. Stark Law - The Medicare/Medicaid Self-Referral Statute

60. The Medicare/Medicaid Self-Referral Statute, 42 U.S.C. § 1395nn, *et seq*., known as the "Stark" law, prohibits a pharmaceutical manufacturer from paying remuneration to physicians for referring Medicaid patients to the manufacturer for certain "designated health services," including drug prescriptions, where the referring physician has a nonexempt "financial relationship" with that manufacturer. 42 U.S.C. § 1395nn(a)(1), (h)(6). The Stark law provides that the manufacturer shall not cause to be presented a Medicaid claim for such prescriptions. The Stark law also prohibits payment of Medicaid claims for prescriptions rendered in violation of its provisions. 42 U.S.C. § 1395nn(a)(1), (g)(1).

61. Pfizer's marketing of Relpax, Geodon, Depo-Provera, and other drugs repeatedly violated the provisions of the Stark law and the False Claims Act because Pfizer's unlawful payments, services, and excessive samples provided to prescribing physicians induced those physicians to prescribe these and other drugs when they otherwise would not have, and many of those prescriptions were paid for by Medicaid and other government funded health insurance programs.

G. Pfizer's Corporate Integrity Agreement with the United States

62. As part of a multi-million dollar settlement agreement in the False Claims Act case of *United States of America ex. rel. David Franklin v. Parke-Davis*, No. 96-CV-11651-PBS (D. Mass), Pfizer, which had acquired Parke-Davis, entered into a Corporate Integrity Agreement with the Office of the Inspector General of the United States Department of Health and Human Services. The qui tam relator's allegations in *Franklin* centered on extensive off-label marketing campaigns for the drug Neurontin and the false claims for government reimbursement that Parke-Davis caused to be filed as a result of its off-label marketing campaign. The Corporate Integrity Agreement, executed by Pfizer on May 11, 2004, requires Pfizer to take numerous internal measures to ensure compliance with FDA regulations of pharmaceuticals, the Federal Anti-Kickback Statute, the False Claims Act, and other federal laws regarding the marketing, promotion, and sale of prescription drugs. Pursuant to the Corporate Integrity Agreement, Pfizer must maintain and enforce, among other things:

a. Published Policies and Procedures that specify methods of selling, marketing, and promoting Pfizer products in compliance with all Federal health care program requirements, including the Federal anti-kickback statute and FDA regulations concerning off-label marketing (§ III.B.2 (b)-(e));

b. Published Policies and Procedures identifying the disciplinary sanctions in place for violations of Pfizer's Policies and Procedures relating to Federal health care requirements and FDA regulations (§ III.B.2 (f));

c. Published Policies and Procedures designed to ensure that consultant arrangements, paid speaking engagements, and related events are used for legitimate and lawful purposes in accordance with federal health care program requirements and FDA regulations regarding the dissemination of information about off-label uses of products (§ III.B.2 (g));

d. Training programs for sales and marketing techniques that do not violate federal health care program requirements or FDA regulations, and training

programs for the gathering, verifying, and reporting of pricing data for State Medicaid Rebate Programs (§ III.C.3 (b)-(c));

e. A Disclosure Program that offers and ensures a non-retaliatory environment for any covered employee who reports suspected violations of FDA regulations and other federal health care program requirements (§ III..E); and

f. A "disclosure log" that includes a record and summary of each disclosure received, the status of the respective internal review, and any corrective action taken in response to the internal review (§ III.E).

63. The Corporate Integrity Agreement also requires Pfizer to notify the Inspector General in writing of any "Reportable Event," defined as any matter "brought to the attention of senior management at Pfizer's New York headquarters that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any federal health care program, and/or any applicable FDA requirement relating to the off-label promotion of drugs" (CIA § III. 4).

64. The Corporate Integrity Agreement further requires Pfizer to file periodic certifications with the Inspector General affirming Pfizer's complete compliance with the terms of the Agreement, including its maintenance and enforcement of the provisions detailed above (§ V.C. 1-3). Upon information and belief, Pfizer has filed at least one, and possibly several, such certifications of compliance with the Inspector General.

65. Each violation of the Corporate Integrity Agreement is subject to a fine assessed per violation and per day of violation ($5,000 for each false certification of compliance issued by the company, for example), but repeated violations of any provision, or Pfizer's failure to notify the Inspector General of a Reportable Event, constitute a material breach of the Corporate Integrity Agreement under § X.D.1. Upon a material breach of the

Corporate Integrity Agreement, the Inspector General may exclude Pfizer from any future participation in all federal health care programs.

V. SPECIFIC ALLEGATIONS OF DEFENDANT'S VIOLATIONS OF LAW

A. Pfizer's Off-Label Marketing and Other Unlawful Marketing Activities

66. Pfizer distributed to Relator and to Pfizer's entire sales force, a "Compliance Cookbook," with an introduction by J. Patrick Kelly, President, Pfizer U.S. Pharmaceuticals. The "Compliance Cookbook" prohibited illegal off-label and other marketing activities. More specifically, it banned "journal clubs" discussing scientific articles, prohibited paying physicians to "train" sales representatives such as the "Technical Tuesday" sessions used in Relator's District, prohibited paying speakers or sponsoring meetings in order to reward high-prescribing physicians, and noted other illegal marketing activities that were prohibited. Nonetheless, many of the prohibited activities mentioned in the Compliance Cookbook continued, even after Relator received his Cookbook on July 30, 2004.

Celebrex and Bextra Marketing

67. Celebrex and Bextra, both formerly marketed by Pfizer, are COX-2 inhibitors. COX-2 inhibitors are a class of drugs which selectively inhibit COX-2, an enzyme involved in the inflammation pathway, while sparing COX-1, thereby causing medical researchers and others to theorize that COX-2 inhibitors had reduced gastrointestinal toxicity as compared to other NSAIDs (nonsteroidal anti-inflammatory drugs). COX-2 selective inhibitors are the newest of the NSAIDs.

68. The risk of gastrointestinal adverse effects increase with higher doses and continued use of NSAIDs, including Celebrex and Bextra. The claims of gastrointestinal superiority of COX-2 inhibitors have never been conclusively established and accepted in the medical

community. It is now known that thousands of patients have died from gastrointestinal bleeding as a result of taking NSAIDS, a known and serious complication associated with NSAID use.

69. Prostaglandins, which are inhibited by NSAIDs, function in the body to protect the stomach lining, promote clotting of the blood, regulate salt and fluid balance, and maintain blood flow to the kidneys when kidney function is reduced. By decreasing prostaglandins, NSAIDs can cause stomach irritation, bleeding, fluid retention, and decreased kidney function. Adverse effects of NSAIDs which can occur at any time include renal (kidney) failure, hepatic (liver) dysfunction, bleeding, and gastric (stomach) ulceration.

70. The risk of gastrointestinal adverse effects increases with every dose of a NSAID, including Bextra and Pfizer's similar drug, Celebrex.

71. Pfizer's repetitious oral and written presentations of off-label and unreliable research data and false conclusions caused physicians to selectively prescribe the far more expensive Bextra and Celebrex, rather than other cheaper drugs, when no real differences existed.

72. Defendant Pfizer's Bextra and Celebrex marketing endangered patients' safety by encouraging non-FDA-approved uses of the drugs. Relator attended several district and team meetings during which Pfizer managers and sales representatives emphasized the importance of securing off-label protocols and standing orders for Bextra and Celebrex.

73. In addition to widespread off-label marketing through protocols and detailing, Pfizer representatives and managers repeatedly made public false claims and misrepresentations about published research results concerning the efficacy and safety of Bextra and

Celebrex, and thereby fraudulently induced physicians and pharmacists to prescribe and seek Federal and State reimbursement for Bextra and Celebrex.

74. In November 2003 and thereafter, Pfizer instructed its sales representatives to falsely promote the relative safety and efficacy of Bextra and Celebrex in response to physician concerns about Vioxx, particularly following wide-spread media coverage regarding Vioxx safety concerns. For example, Relator's supervisor, Michael Krams, directed Relator, when facing physician questions regarding Bextra's safety, to cite the unpublished Solomon Study.[1] Relator was also told by Mr. Krams to tell physicians that the problems with Vioxx were not class-wide problems and did not, therefore, apply to Celebrex or Bextra.

75. Pfizer sales managers paid physicians to speak regarding off-label uses of Bextra and Celebrex. At the May 28, 2003, Pfizer Plan of Attack meeting, Mr. Krams instructed representatives to pay physicians to serve as speakers for off-label promotion to induce physicians to place standing orders for Celebrex to be used for off-label uses promoted by Pfizer. Relator attended several such promotional events in which physicians discussed off-label uses of Bextra such as post-surgical uses and the effects of Celebrex and Bextra on bone healing and bone grafts. In order to obtain approval for payments to physicians for attending such off-label promotional events, sales representatives, with the approval of their managers, falsified documents claiming that the programs pertained to topics approved by Pfizer in advance.

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[1] "The Solomon Study" or "Solomon Article" by Daniel H. Solomon; Sebastian Schneeweiss; Robert J. Glunn; Yuka Kiyota; Raisa Levin; Helen Mogun; Jerry Avorn entitled Relationship Between Selective Cyclooxygenase-2 Inhibitors and Acute Myocardial Infarction in Older Adults, later published in *Circulation* 2004: 109; 2068-2073.

76. On August 27, 2003, District Manager Krams announced that the sales representatives would all be participating in a new weekly journal club, beginning September 5th at 7:30 a.m. The teleconferences were called "Technical Thursdays." Scientific articles that stated "do not detail" and which Pfizer prohibited from being used by sales representatives in detailing ("Pfizer restricted") were nonetheless used in this new training on off-label technical issues. The training sessions were intended to prepare representatives to detail the contents of off-label studies and to answer physician inquiries about off-label uses.

77. In September 2003, Relator and other sales representatives across the country received materials created by Pfizer's Best Practices division in Portland, Oregon describing how to market Bextra and Celebrex off-label for pre-operative and post-operative treatments. This training document, dated July 23, 2003 and entitled "COX-2 Protocols and Standing Orders Best Practices" was "homemade," in that it was apparently developed by non-corporate offices at Pfizer and not approved by Pfizer's Product Review Committee nor provided to the FDA, as required by law. Thus, the use of these materials and related training of sales representatives violated Pfizer policy and FDA laws and regulations. Notwithstanding the prohibitions on using homemade documents, this document was distributed to sales representatives nationally and the information within the training document was used to promote off-label uses of Bextra and Celebrex. Pfizer's upper-level management knew or should have known that this training occurred.

78. In January 2004, at one of Pfizer's periodic "Plan of Attack" meetings attended by District Manager Mike Krams and approximately 9 other district sales representatives, Relator received a 2004 Business Plan from a Pfizer sales representative. This Plan was approved by Mr. Krams and required the representative to "Establish a Minimum of 11

Physician Protocols by July 31, 2004." On that same page, one "Strategy" for obtaining Bextra protocols included calling upon anesthesiologists in Ohio and West Virginia for the purpose of obtaining off-label sales of Bextra and Celebrex for post-operative pain. This section of the Pfizer-approved sales plan was called "Anesthesiology - Zanesville, Parkersburg."

79. In the spring of 2004, the Ohio State Medicaid agency dropped Vioxx from its formulary list of drugs approved for reimbursement, but both Bextra and Celebrex were still approved for prescription use. Pfizer Sales Managers insisted that sales representatives tell physicians that the Ohio Medicaid decision was based on Bextra's superior efficacy and faster onset time (time between ingestion and first signs of pain relief). Pfizer's management received at least one formal complaint of harassment, which was tape-recorded, when an Ohio sales representative refused to follow these instructions for off-label marketing of Bextra and Celebrex.

80. In May 2004, Pfizer upper level management initiated a compliance training program to teach sales representatives that it was illegal and against Pfizer company policy and FDA regulations to use false comparative claims of superiority and to promote and detail off-label studies addressing superiority or unapproved dosages or indications. This program came after more than a year of training sales representatives to promote Bextra and Celebrex for off-label uses (by, *inter alia*, making untrue claims about the superior efficacy and safety of those drugs), and repeated failures to respond to, or take action regarding, Relator's multiple reports to Pfizer's management and compliance officials of off-label marketing of Bextra and Celebrex. Pfizer also began issuing prohibitions on sales personnel submitting false certifications of physician requests for scientific

information from Pfizer's Medical and Drug Information unit. In the May 2004 compliance training, Pfizer representatives were warned that false certifications of requests for Medical and Drug Information could lead to representatives being prosecuted criminally. All employees were required to sign documents stating that they had completed the compliance training and agreed to abide by the Pfizer compliance rules. The signed documents were retained by Pfizer's New York-based compliance officers.

81. Pfizer's May 2004 compliance training did not end off-label promotion and was little more than "window-dressing." Within hours of the new Pfizer compliance training in May 2004, Relator observed Pfizer's regional and district managers training representatives in off-label marketing and other practices that were prohibited by internal company guidelines just reviewed in the compliance training. Specifically, District Manager Krams made statements about Bextra's superiority to Vioxx, despite the lack of required substantial scientific evidence to support his statements. At that time, a Pfizer senior hospital representative also told the assembled sales staff that Celebrex was superior to naproxen. When Relator spoke up in order to correct this false statement, Mr. Krams claimed the hospital representative's statement was true and instructed the District Managers to ignore Relator's statements. In addition, Mr. Krams told representatives to continue using the Solomon Study, through detailing and proactive promotion of Pfizer's Medical and Drug Information regarding cardiovascular safety, a practice that also directly violated the training the representatives had just received. Pfizer's district and regional management persistently encouraged off-label protocols and standing orders for Celebrex and Bextra in both team meetings and internal company documents, continuing even after the May 2004 compliance training.

82. In September 2004, Pam Robertson, Assistant to the Regional Director of Pfizer's Alta Division, instructed Relator to promote Bextra and Celebrex as having superior efficacy because they were better tolerated and safer than other alternative drugs, in direct contradiction to Pfizer's May 2004 compliance training. When Relator questioned this instruction, Ms. Robertson persisted, stating that these instructions had come directly from her own training from Pfizer Executive Vice President Rick Birch.

83. Pfizer's marketing schemes included efforts to expedite the States' Medicaid prescription approval process for Bextra and Celebrex. Restricted state formularies listing drugs that particular Medicaid programs provided to patients often required prior authorization in order for physicians to prescribe certain expensive drugs, like Bextra and Celebrex. Without such authorization, physicians and patients would likely have resorted to less expensive over-the-counter alternatives, such as NSAIDs like ibuprofen or naproxen. From May 5, 2003 until March 2006, Pfizer District Managers directed subordinates to procure Ohio Medicaid "Prior Authorization" forms from an internet website, make multiple copies, give them to physicians, and assist physician offices in completing them for patients so that Ohio Medicaid would approve Celebrex prescriptions and, prior to its removal from the market, Bextra prescriptions. District Manager Krams conducted trainings in which he explained how to use Medicaid prior authorization forms. Some managers provided representatives with stamping devices with pre-printed prior authorization information for Bextra and Celebrex so that physicians or representatives could simply stamp the information onto the Pfizer-provided forms. Representatives were instructed to make sure that there was nothing identifying the forms as Pfizer-created. Representatives were told to carry these forms with them on all of their sales

calls. In some instances, Pfizer sales representatives filled out the forms themselves or even called Ohio and other state Medicaid offices to obtain authorization. These authorization forms were "homemade" and thus illegal because they were copied from the Ohio Medicaid website and were not approved by Pfizer's Product Review Committee nor approved by or filed with the FDA. Specific directions by Mr. Krams to distribute the pre-approval forms were given on the following dates: June 23, 2003; August 6, 2003; November 19-21, 2003; and January 28, 2004.

B. Bextra

84. Valdecoxib, an anti-inflammatory drug manufactured and marketed by Pfizer under the brand name "Bextra," is indicated for the treatment of pain and inflammation associated specifically and only with rheumatoid arthritis, osteoarthritis, and primary dysmenorrhea (a type of menstrual pain). The FDA approved Bextra for these uses on November 16, 2001. The FDA never approved Bextra for any other uses. Pfizer was thus prohibited from actively marketing Bextra for any use other than its initial FDA-approved uses.

85. Bextra was a COX-2 selective inhibitor and has been discontinued. The FDA approved Bextra at doses of 10mg for chronic arthritic pain and approved short-term, intermittent use of Bextra at the larger dose of 20mg for menstrual pain. No higher dose of Bextra was ever approved by the FDA. However, Pfizer sales representatives were trained to promote and promoted doses as high as 40mg as safe and more effective than the FDA approved doses of Vioxx and other products. On November 16, 2001, the FDA specifically rejected Pfizer's application for approval of Bextra for the treatment of acute pain.

86. The FDA has never approved the claim that Bextra provided superior gastrointestinal safety.

87. In April 2005, following FDA concerns about the safety of Bextra, Pfizer completely withdrew Bextra from the market.

88. At least as early as May 2003, and continuing through at least July 2004, Pfizer sales representatives and district managers engaged in a variety of organized marketing techniques in an effort to promote unapproved, off-label uses of Bextra for unapproved treatments and at unapproved dosages. These efforts were designed to increase Pfizer's sales of the drug and violated FDA regulations prohibiting these off-labeI marketing and other illegal marketing activities. Relator, in his position as a Pfizer Senior Pharmaceutical Sales Consultant, personally witnessed these tactics being used to illegally procure Bextra sales. Relator was also informed by his Pfizer colleagues and superiors of these illegal marketing efforts aimed at improperly influencing physicians to prescribe Bextra for unapproved uses and thereby increasing sales and increasing potential harm to patients. These and other unlawful marketing activities caused false claims to be submitted to the United States for payment.

89. Pfizer management actively encouraged sales representatives to solicit Bextra medical protocols or "standing orders," that is, written standardized treatment plans applicable to all patients whose conditions met certain physician-established criteria and that called for the prescription of Bextra for such non-approved, off-label uses as pain associated with laser refractive eye surgery, carpal tunnel surgery, ankle fracture repair, and soft tissue surgery.

90. An internal memo, dated July 24, 2003, from a Pfizer hospital sales representative to Relator's team of representatives and Relator's District Manager, Mike Krams, discussed medical protocols and attached sample protocols for off-label uses to assist sales

representatives in encouraging physicians to issue similar off-label protocols. Each protocol or standing order is especially significant to Bextra sales because, as the memo explains to representatives, "once it is set in place it is a prescription that keeps giving even when you are not in the office asking for the business."

91. On or around May 10, 2003, Relator and many other Pfizer sales representatives, all of whom formerly worked for Pharmacia, attended a national training in Detroit, Michigan. At the training session, Pfizer trained its representatives to include, as targets for Bextra sales, primary care physicians, physician assistants, and nurse practitioners, all of whom treat pain associated with rheumatoid arthritis, osteoarthritis, and primary dysmenorrhea (menstrual pain). Pfizer also urged sales representatives to market Bextra to providers who only treated more acute pain associated with injuries or surgery, such as orthopedic physicians, oncologists, eye surgeons, spine surgeons, plastic surgeons, and anesthesiologists.

92. Although the 20mg dose of Bextra was only approved for dysmenorrhea, most Pfizer Specialty Representatives were given significant numbers of 20mg samples to provide to physicians. These Specialty Representatives did not call upon gynecologists and primary care providers, the types of physicians likely to treat menstrual pain. Instead, the Specialty Representatives called on particular medical specialty practices, such as orthopedic surgeons and pain management specialists who did not treat menstrual pain. These Specialty Representatives thus delivered 20mg samples to physicians specializing in pain management and orthopedic surgery, even though the 20mg dose of Bextra was not approved for conditions treated by these physicians.

93. Relator's handwritten notes from an August 27, 2003 meeting with Pfizer District Managers and sales representatives, as well as other notes and orders in Relator's possession, reflect a protocol for marketing the 20mg Bextra doses to the Columbus Blue Jackets, an all-male National Hockey League professional hockey team. The Blue Jackets did not treat its players for menstrual pain, but the players would experience pain from injuries or surgery.

94. In the last half of 2003, Pfizer sales personnel provided Relator and other Ohio and West Virginia sales representatives with copies of an internal letter from a physician to an athletic trainer who treated players on the Columbus Blue Jackets professional hockey team. The letter detailed standing orders for 20mg Bid (twice daily) doses of Bextra for acute pain. This was an off-label use, as the FDA had previously rejected Pfizer's application for use of Bextra for acute pain and did not approve its use at doses of 20mg for any pain other than menstrual pain, which occurs only in women.

95. The Columbus Blue Jackets' physician's September 5, 2003 letter about Bextra to the team's trainer was not approved for marketing use by Pfizer's Product Review Committee. The letter alludes to important safety concerns with traditional NSAIDs and suggests that Bextra should be used as an alternative. These safety concerns, as articulated in the letter, related to traditional NSAIDs and were not supported by substantial scientific evidence. There was inadequate scientific support for the suggestion that Bextra was a suitable and safe alternative. Thus, the letter could not qualify for approval by Pfizer's Product Review Committee. Nonetheless, it was not properly marked by Pfizer to indicate that it should not be used in the field with other doctors, who might well be greatly influenced by the medical opinion. District Manager Krams

instructed Pfizer representatives to use the September 5, 2003 letter as highly influential marketing material for promoting off-label use of Bextra for acute pain. Many sales representatives followed this directive, thereby causing false claims to be submitted to the government for payment.

96. Bextra was never approved for pre-operative or post-operative treatment, nor for use in any way with anesthesia.

97. Pfizer's own intranet information site, the "Pfizer World Café," acknowledged that in February 2005 Bextra was not indicated in the U.S. for post-operative pain and, in fact, was "contraindicated in its U.S. and European labels for the treatment of post-operative pain immediately following CABG [coronary artery bypass graft] surgery due to an observed increased risk of cardiovascular event during the trials." However, Pfizer aggressively marketed Bextra for pre and post-operative treatments, without taking care to be sure that its marketing included the appropriate FDA-required restrictions applicable to post-operative pain resulting from CABG surgery.

98. Pfizer repeatedly trained and encouraged sales representatives to engage in unlawful "detailing" with regard to Bextra. Detailing is the common pharmaceutical sales practice of summarizing the highlights and findings of particular medical reports or clinical studies in order to pitch a drug to physicians and pharmacists.

99. Despite FDA law and official Pfizer policies, at the Pfizer Great Lakes Regional sales meeting held November 17-19, 2003, Pfizer sales representatives were trained and encouraged to refer to and summarize off-label studies as part of their rehearsed detailing of Bextra. Relator's District Manager, Michael Krams, also emphasized as a key action item for Bextra sales that representatives proactively send to "all Vioxx targets," through

Pfizer's Medical and Drug Information unit, unpublished research by Dr. Daniel H. Solomon. Dr. Solomon's research ostensibly showed, among other things, that preliminary data indicated that patients taking Celebrex experienced statistically fewer incidents of myocardial infarction than patients taking Vioxx during the first 90 days of use. The research also showed that there was no statistical difference between either Celebrex or Vioxx and traditional NSAIDS in incidents of myocardial infarction during the first 90 days. Thus, Dr. Solomon's study did not concern Bextra, nor had it been published prior to its circulation amongst Pfizer sales representatives. However, Pfizer circulated the Study to its sales representatives four months before it was published. Dr. Solomon's Study was not approved by Pfizer's Product Review Committee for the purpose of detailing until November 2004 and then was quickly withdrawn.

100. Despite the many deficiencies in the unpublished Solomon Study, at the direction of District Manager Krams, Relator prepared a summary of the November 2003 strategy meeting for Regional Director Steve Reese, Alta Division, and Mr. Krams. The DeMott notes included Mr. Krams' plans for Pfizer's Medical and Drug Information unit to engage in off-label promotion of Bextra. The memo states:

> Key Item: Send Solomon medical inquiry to all Vioxx targets
>
> * *
>
> Action Item: SEND MED INQ TO VIOXX OFFENDERS

101. The November 2003 strategy meeting directed Pfizer sales staff how to respond to any physician comments to the effect of "I don't see increase in hypertension and edema with Vioxx." Mr. Krams wanted representatives to respond orally to the physicians with information taken directly from the unpublished Solomon Study and Pfizer's Medical

and Drug Information unit because those sources contradicted Merck's sales representatives' claims that Vioxx presented cardiovascular issues only after 18 months of high-dose use.

102. Pfizer's Medical and Drug Information presentation of the unpublished Solomon Study as a head-to-head comparison of Celebrex with Vioxx (which it was not) and as a published peer review article (which it was not) was misleading. In addition, characterizing the study in this fashion was a significant promotional advantage for Celebrex over other competitor's drugs in the class. Pfizer's promotional use of the Solomon Study also was intended to increase sales for Bextra because the sales message was that Vioxx's safety issues did not affect the entire Class of COX-2 drugs.

103. In an August 27, 2003 Pfizer Mid-district Plan of Attack meeting in Ohio, Pfizer sales management directed its sales representatives to focus on physicians who were prescribing Vioxx instead of Bextra. Pfizer also instructed its representatives to review articles by James Fricke, F. Camu, and Stephen E. Daniels, D.O. These articles all involved off-label Bextra use and misrepresent the efficacy of Bextra, particularly in comparison to Vioxx.

104. Dr. Fricke's article[2] claimed that for pain associated with oral surgery, 40mg of Bextra twice daily provided superior relief in comparison to 50mg of Vioxx. This was an off-label use because Bextra was never approved for use at 40mg and was not approved for any acute pain or for dental pain. Pfizer's Product Review Committee had rejected this

[2] "The Fricke Study" or "Fricke Article" by James Fricke, John Farkalis, Sam Zwillich, Rebecca Alder, Elliot Forester, David P. Recker, and Kenneth M. Verburg, entitled Valdecoxib Is More Efficacious Than Rofecoxib in Relieving Pain Associated with Oral Surgery, published in *American Journal of Therapeutics* 9, 89-97 (2002).

study as unreliable and restricted the article so that it was not to be made available to the Pfizer sales force. The study was based on a flawed methodology of comparing an FDA-approved dose of Vioxx to an unapproved dose of Bextra. Nonetheless, this study was included in the articles to be relied upon by sales representatives in the Plan of Attack meeting and was again reviewed by representatives in a district-wide technical training teleconference held on September 25, 2003. This teleconference was held by District Manager Krams and included 9 representatives from the Capitol District, Great Lakes Region, and Alta Division.

105. Dr. Daniels' study,[3] which reviewed the effectiveness of Bextra as compared to oxycodone/acetaminophen (Percocet) for oral surgery, was approved by Pfizer's Product Review Committee for restricted, off-label dissemination only, but, until at least May 2004, continued to be used by management and sales representatives for direct detailing to physicians to market off-label the 40mg dose of Bextra.

106. Dr. Daniels' study is fundamentally flawed and violated FDA standards requiring comparisons between different drugs to be based on comparable dosages and for articles to have clinical relevance. Contrary to these FDA requirements, the Daniels Study concluded that, over 24 hours, a single dose of 20mg or 40mg Bextra was superior to a single dose, 10mg oxycodone/acetaminophen 1000 mg (Percocet), in relieving acute post-surgical pain. This comparison was extremely misleading since the effectiveness of oxycodone/acetaminophen diminishes in only 6 hours. Studies already had shown that a

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[3] "The Daniels Study" or "Daniels Article" by Stephen E. Daniels, D.O.; Paul Desjardins, D.M.D.; Sheela Talwalker, Ph.D.; David P. Recker, M.D.; Kenneth M. Verburg, Ph.D., entitled The Analgesic Efficacy of Valdecoxib vs. Oxycodone/Acetaminophen after Oral Surgery, published in *The Journal of American Dental Association*, Vol. 133 May 2002.

single dose of the relatively short-acting Percocet would not be effective over a long period of time in treating pain and, thus, Percocet was rarely, if ever, prescribed once-daily for acute post-surgical pain.

107. In 2002, Dr. Eric J. Topol of the Cleveland Clinic and two other scientists publicly discredited the Daniels Study and questioned whether it was contrived to yield a favorable result for Bextra. Even after this, Pfizer repeatedly trained Relator and the company's entire sales force that the Daniels Study represented qualified, reliable research. Pfizer used the study in 2003 and 2004 and thereafter to promote Bextra.

108. Pfizer sales representatives were repeatedly instructed to tell physicians that Bextra provides "rapid and powerful relief in 26 minutes." This claim is based upon the misrepresentation of data contained in Table 3 of the published Daniels Study, where it represents that the 95% confidence interval for analgesic relief, using the 40mg dose of Bextra (2-4 times the approved dose), ranged from 26 to 34 minutes. The Daniels Study Table 3 in fact shows the median time for pain relief was 28 to 34 minutes for Bextra and 28 to 29 minutes for Percocet. Not only is the promise of Bextra speeding pain relief in a superior manner a misleading statement, the FDA-approved package insert specifically states that Bextra works in less than 60 minutes for primary dysmenorrhea, consequently making the "26 minute" message an illegal and off-label promotion.

109. The Camu Study,[4] which concludes that Bextra, including pre-operative use of Bextra, reduces the amount of morphine required for post-operative pain relief and provides

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[4] The "Camu Study" or "Camu Article" by F. Camu, T. Beecher, D.P. Recker and K.M. Verburg, entitled Valdecoxib, a COX-2-Specific Inhibitor, Is an Efficacious, Opiod-Sparing Analgesic in Patients Undergoing Hip Arthroplasty, published in *American Journal of Therapeutics* (2002) 9:43-51.

greater analgesic efficacy compared to morphine alone, was approved by Pfizer's Product Review Committee for off-label dissemination to physicians, but not for detailing. This study's cover page, as used by Pfizer in promotion, fails to advise the reader that Bextra is not indicated for pre-operative and post-operative administration and use. Use by Pfizer's sales representatives, with the approval of Pfizer's Product Review Committee, violated FDA regulations and Pfizer policies. Nonetheless, at the direction of Pfizer management, the Camu Study was directly detailed to physicians by sales representatives and was used to illegally influence physicians' independent medical decision making.

110. Pfizer sales representatives relied heavily on an article by P.T. Leese,[5] which claimed that Bextra does not impair platelet function, a significant advantage over traditional NSAIDs for pre-operative and post-operative use. The Leese Study was approved by Pfizer's Product Review Committee for off-label dissemination only and not for active promotion. Nonetheless, information from this study was included in Pfizer's 2003 "Plan of Attack" materials provided to sales representatives across the nation so that they could promote Bextra as having "no effect on platelet aggregation" and use the Leese Study as a selling tool. Pfizer sales management trained its field staff to promote off-label indications with this article, resulting in off-label Bextra prescriptions and false claims submitted to the government for payment.

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[5] The "Leese Study" or "Leese Article" by P.T. Leese, S. Talwalker, J.D. Kent and D.P. Recker, entitled Valdecoxib Does Not Impair Platelet Function, published in *Am J. Emerg Med* (2002) 20:275-281.

111. Regional Pfizer management encouraged dissemination of false information and unlawful marketing practices. For example, in May 2003, District Manager Krams included in the sales representatives' materials a general schematic drawing approved by Pfizer's Product Review Committee to explain the way NSAIDs and COX-2 inhibitors worked on the central nervous system. Mr. Krams extrapolated this general information into misleading claims that Bextra's pain relief function was superior to Vioxx and that the research showed that Bextra works on the central nervous system whereas NSAIDs and Vioxx were not as effective in the brain.

112. Relator informed Mr. Krams in May 2003 and thereafter that superior efficacy claims were not supported by the research and that Relator would not make such claims to physicians, nor make any superior "brain" claims about Bextra. In the summer of 2003, Relator confirmed his understanding that these claims of superior efficacy in pain treatment were false. He met with Dr. Brian F. Griffin, an expert in pain management, and showed him the schematic that Mr. Krams had directed district sales representatives to put in their sales detail binder, which was a notebook regularly used in marketing calls upon physicians, and to use in detailing Bextra to physicians. Dr. Griffin explained that such claims about the superior efficacy of Bextra based on its effects on the brain were misleading and that they misrepresented the current state of professional knowledge about pain management. A second physician, Dr. Joseph Flood, a well-respected rheumatologist and Pfizer speaker, also debunked the "brain" superiority claims.

113. In the summer of 2003, Relator told Mr. Krams that Dr. Griffin rejected these claims of superior Bextra efficacy. Mr. Krams, however, continued to pressure Relator and other sales representatives to tell physicians that Bextra was superior to Vioxx and to focus on

Bextra's effect on the brain and speed of onset as important information regarding efficacy, despite the lack of any credible scientific evidence to support these claims. Relator responded by advising District Manager Krams that Dr. Flood said that the "brain" claims, even if true, would have no relevance in treating osteoarthritis and rheumatoid arthritis.

114. Relator witnessed and documented repeated uses of off-label studies in detailing Bextra. This improper marketing resulted in physicians writing prescriptions for off-label uses that otherwise would not have been issued. Pfizer regional management demanded such aggressive off-label promotion, as demonstrated by instructions to sales representatives in selling points based on off-label studies at the Pfizer November 17-19, 2003, Great Lakes Regional Meeting.

115. In October 2003, Mr. Krams instructed representatives to target doctors who prescribed Vioxx by claiming that Bextra was safer and more effective. As part of this marketing effort, Mr. Krams directed representatives to misleadingly promote Bextra's cardiovascular safety and efficacy to physicians prescribing Vioxx and provide the physicians with Bextra samples containing 30 units in each container. If the representatives did not have enough sample containers with 30 units, they were instructed to empty smaller containers of samples into plastic bags containing 30 units each, in order to continue the promotion. Thus, representatives were not only making unsubstantiated claims about safety and efficacy, they were also misbranding the drug by putting samples in bags, without FDA-approved package inserts. Relator repeatedly reported this practice to Pfizer's compliance employees, but Relator was not aware of

any action taken to stop this practice, until much later in time. This sampling effort was engineered and directed by sales managers.

116. At the Pfizer November 2003 Great Lakes Regional Strategy Synergy Meeting, Relator and the other sales representatives attending were given a strategy document, referred to internally as the "Chunnel Agreement." The Chunnel Agreement summarized various articles advocating off-label uses of Bextra, including the Daniels and Camu Studies, for direct sales promotion with physicians. The Chunnel Agreement also misrepresented the conclusions of the Solomon Study by falsely claiming that it showed that the cardiovascular problems with Vioxx were not a Class effect applicable to all COX-2 medications. At the meeting, Pfizer district managers directed sales representatives to refer to these pieces in their detailing, and in fact, these articles were designated as "Key Clinical" for promotion.

117. The November 2003 Pfizer Chunnel Agreements instructed sales representatives that the "Core Message" for Bextra promotion should be that Bextra provides "Rapid Powerful Relief in 26 minutes." No clinical data approved by Pfizer's own Review Committee supported this claim and the claim conflicts with the information in the FDA-approved label and package insert. The Core Message also taught representatives to claim that Bextra was more effective than Vioxx, an assertion which lacked recognized clinical support and was in violation of FDA regulations on comparative marketing statements. Representatives and managers throughout the 5 states in the Great Lakes Region were thereby trained to make false claims and misrepresent product qualities to physicians and pharmacists, in an effort to increase Bextra's market share and in violation of FDA

regulations, Pfizer's Corporate Integrity Agreement, the Food, Drug and Cosmetics Act, and state laws.

118. On many occasions, Relator discussed with other senior Pfizer sales representatives the impropriety of including off-label studies in their detailing and other marketing activities prohibited by FDA law. In response, Relator was informed by several representatives that they would not stop what they knew to be illegal behavior because their District Managers expected them to continue. Specifically, representative Brandee Trout told this to Relator on numerous occasions, including in September 2004. Two other representatives made similar statements to Relator after 2004 teleconferences and regional meetings. A Pfizer hospital sales representative told Relator that she asked Mr. Krams if the use of these off-label studies was legal and he assured her that it was.

119. In February 2004, Pfizer District Manager Melissa B. Cohen instructed a sales representative to refer to the Fricke Study in detailing Bextra, despite the fact that the Product Review Committee had rejected this study and restricted its use. When reported to Relator, he advised the representative to stop immediately and explained the FDA and Pfizer restrictions on using the Fricke Study. Ms. Cohen later acknowledged that the Fricke Article involved off-label use of Bextra, but insisted that it be used and to practice detailing this study on voice mail messages provided for her review. The sales representative reported this off-label use to his Pfizer Regional Director and Pfizer's home office management.

120. On a May 6, 2004 conference call with several Pfizer regional sales representatives, a senior representative announced to the group that she would not stop explicitly referring to off-label studies in her detailing until her district manager expressly told her to do so.

During this conference call she stated that Pfizer District Manager David Musci personally assisted her in conducting the off-label detailing to physicians.

121. Relator repeatedly reported in 2003 and 2004 to District Manager Krams that Pfizer's claims about Bextra were false, in the presence of his entire district sales force. Relator later reported the same to Pfizer's national compliance officers in New York.

122. In August 2004, after Pfizer District Manager Krams participated in an internal company investigation of marketing activities, he admitted to Relator that he believed that the "Core Message" that Bextra works in 26 minutes was false. Relator asked Mr. Krams why he did nothing when Relator brought the problem to his attention many times previously. Mr. Krams stated that higher management trained and directed him to convey this "Core Message."

123. A few weeks after Relator's August 2004 Bextra "Core Message" conversation with Mr. Krams, Pam Robertson, Assistant to Pfizer's Regional Director, told Relator that the Bextra and Celebrex detailing instructions that he was objecting to had come directly from Rick Birch, Pfizer's Vice President and Director of Pfizer's Cluster A sales force. She further stated that Relator would be "in trouble" for not following Mr. Birch's instructions. Relator conveyed this conversation to Pfizer's compliance officers.

124. On February 25, 2004, while Relator, another sales representative, and District Manager Krams were paying a sales call to a physician, the doctor asked why he should use Bextra instead of Vioxx. Mr. Krams answered that Bextra has "narcotic-like pain relief" because it works "in the brain on the central nervous system." Relator challenged Mr. Krams following the meeting, but Mr. Krams stood by his statement and directed Relator to a

clinical study by Dr. Makarowski.[6] That study states merely that Bextra, like all COX-2 drugs, including Vioxx, has some effect on brain and central nervous system activity, but the study provides no support for Mr. Krams' bold claim that Bextra is superior in efficacy to Vioxx and other NSAIDS.

125. Relator witnessed instances where representatives were instructed to make unsubstantiated claims that Bextra provided superior patient safety, particularly superior gastrointestinal safety. In November 2003, Pfizer's training materials for the national sales force included off-label detailing that directed representatives to make claims of superior gastrointestinal safety based on flawed and misleading representations of results of various studies, including those referenced in this complaint. These claims of superior gastrointestinal safety, which were included in the company's nationally-approved training materials, contradicted warnings on Bextra's FDA approved package insert and were not supported by the substantial scientific evidence required by the FDA to support claims of comparative safety or efficacy.

126. Pfizer's aggressive marketing of Bextra for off-label uses for acute pain, chronic pain, pre-operative and post-operative pain, dental pain, and podiatric pain, as well as its promotion at doses higher than approved by the FDA, caused physicians and health care professionals to prescribe and seek reimbursement from Federal and State health care programs for Bextra for off-label uses. Moreover, Pfizer's repeated marketing of Bextra as having superior safety benefits caused physicians to prescribe the drug more frequently

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[6] W. Makaroski, William W. Zhoa, Terry Bevirtt, David P. Reckert, entitled Efficacy and Safety of the COX-2 specific inhibitor valdecoxib in the management of osteoarthritis of the hip: a randomized, double-blind, placebo-controlled comparison to naproxen, published in *Osteoarthritis and Cartilage* (2002) 10:290-296.

and to exercise less caution than would be warranted by the FDA-approved package insert, thus putting patients at additional risk.

127. Every reimbursement sought from Medicaid and other government health care programs for purchases or prescriptions of Bextra as a result of Pfizer's false, exaggerated, or insufficiently supported efficacy and safety claims constitutes a false claim under the False Claims Act.

128. On April 7, 2005, the FDA asked Pfizer to withdraw Bextra from the market "because the overall risk versus benefit profile for the drug is unfavorable." (FDA press release). The FDA also issued a Public Health Advisory that elaborated on its bases for requesting that Pfizer withdraw Bextra, including the FDA's findings of increased incidents of cardiovascular events associated with coronary artery bypass surgery. By inducing physicians to write prescriptions for off-label uses of Bextra, Pfizer exposed patients to these same risks and side effects that led the FDA to request Bextra's withdrawal.

C. Celebrex

129. Celelecoxib is a non-steroidal anti-inflammatory COX-2 inhibitor manufactured and marketed by Pfizer under the brand name "Celebrex." Pfizer was prohibited from actively marketing Celebrex for any use other than its FDA-approved uses and was prohibited from making unapproved comparative claims or unapproved product quality claims.

130. On December 31, 1998, the FDA first approved Celebrex for these two indications:

* For relief of the signs and symptoms of osteoarthritis.
* For relief of the signs and symptoms of rheumatoid arthritis in adults.

131. On December 23, 1999, the FDA approved Celebrex for treatment of Familial Adenomatous Polyposis (FAP) as set forth in the approved label:

> To reduce the number of adenomatous colorectal polyps in familial Adenomatous polyposis (FAP), as an adjunct to usual care (e.g., endoscopic surveillance, surgery). It is not known whether there is a clinical benefit from a reduction in the number of colorectal polyps in FAP patients. It is also not known whether the effects of CELEBREX treatment will persist after CELEBREX is discontinued. The efficacy and safety of CELEBREX treatment in patients with FAP beyond six months have not been studied (See CLINICAL STUDIES, WARNINGS and PRECAUTIONS sections).

132. On October 18, 2001, the FDA approved Celebrex for the treatment of primary dysmenorrhea (severe menstrual pain) and for the management of acute pain in adults. The label further defined the acute pain as "post-oral surgery pain, post-orthopedic surgical pain…"

133. On July 29, 2005, the FDA approved Celebrex "For the relief of signs and symptoms of ankylosing spondylitis." On December 15, 2006, the FDA's approval letter stated that Celebrex is indicated "for the relief of the signs and symptoms of juvenile rheumatoid arthritis (JRA) in patients 2 years of age and older."

134. The FDA never approved Celebrex for treatment of any other conditions except those enumerated above. There was never a generalized approval of use for chronic pain, nor for general pre-operative and post-operative surgical treatment.

135. The FDA approved Celebrex at doses of 100mg-200mg for rheumatoid arthritis and 200mg for osteoarthritis. The FDA approved Celebrex for Juvenile Rheumatoid Arthritis at doses of 50mg-100mg based on the child's weight. For the treatment of primary dysmenorrheal and certain acute pain, the FDA approved a larger initial dose of 400mg, followed by decreased 200mg doses. For the treatment of Familial Adenomatous Polyposis (FPA), a significant dose of 400mg twice daily was approved. Celebrex was

also approved for the treatment of Ankylosing Spondylitis, at a high dose of 200mg twice daily.

136. Pfizer's original label, as approved by the FDA in December 1998, had no statements about Celebrex's superior gastrointestinal safety, but carried a warning of gastrointestinal risks of ulceration, bleeding, and perforations. The risks stated in the package insert apply as a Class warning involving all non-steroidal anti-inflammatory drugs (NSAIDs).

137. Pfizer intentionally and falsely trained its Celebrex sales force to tell physicians that Celebrex provided superior pain relief as compared to Vioxx and NSAIDs, even though Pfizer's official and approved slide set for speakers used in 2002 confirmed that Celebrex and ibuprofen worked about equally well.

138. In the summer of 2000 or 2001, Relator DeMott, as one of the top-producing Celebrex sales representatives in the United States, was invited to a meeting at Pfizer's New Jersey offices, along with about 10 other Celebrex representatives. The results of a scientific study, commonly referred to as "The Class Study,"[7] were discussed by a Celebrex product team member who held a doctorate in pharmacy. He stated that the study failed to meet its primary research objective or "primary endpoint" because it did not show a statistically significant lower incidence of complicated ulcers for patients using Celebrex when compared with other drugs. The speaker stated the incidence of low-dose aspirin use was nearly twice as high as the researchers had expected in the patient population for this

[7] "The Class Study" by F.E. Silverstein, G. Faich, J.L. Goldstein, L.S. Simon, T. Pincuc, A Whelton R. Makuch, G. Eisen, N.M. Agrawal, W.F. Stenson, A.M. Burr, W.W. Zhao, J.D. Kent, J.B. Lefkowith, K.M. Verburg, G.S. Geis, entitled Gastrointestinal Toxicity With Celecoxib vs. Non-Steroidal Anti-Inflammatory Drugs for Osteoarthritis and Rheumatoid Arthritis, the Class Study: A Randomized Controlled Trial, published in the *Journal of the American Medical Association* (2000) 284:1247-1255.

study. Aspirin use is a risk factor for increased gastrointestinal complications by itself. He theorized that the study failed to show Celebrex's superiority because there was a higher rate of low-dose aspirin use in the patient population being researched than the scientists expected, thus increasing gastrointestinal complications in the Celebrex group. The Pfizer speaker said that with these study results the company could not claim superior efficacy to competitor drugs and would not be entitled to claim superiority under FDA rules and regulations. The representatives were asked to discuss with the group of managers what impact the lack of superiority as to gastrointestinal safety would have upon their Celebrex sales.

139. In 2001, Pfizer trained representatives to promote Celebrex using fabricated claims of superior gastrointestinal safety and a restricted training piece entitled "Key Selling Points of Celebrex." The Pfizer Review Committee apparently did not approve this training document. Part of the document contained information derived from the Class Study that is unsubstantiated and false regarding superior gastrointestinal safety. Using the Class Study, Pfizer management and marketing teams trained sales representatives to make overly general superiority claims about Celebrex in relation to other NSAIDs, claims that were not supported by the data. Pfizer trained the sales force to claim that Celebrex provided superior upper gastrointestinal safety and a superior tolerability profile as compared to other NSAIDS, even though there was no FDA-approved scientific data supporting the claim.

140. In April 2002, Pfizer trained its Celebrex sales force, using written materials not filed with the FDA, to claim to physicians that the Class Study showed that Celebrex was superior in gastrointestinal safety to naproxen, ibuprofen, and diclofenac.

141. In 2002-2004, Pfizer used the Class Study, with a blue over stamp until April 15, 2003, to mislead its sales representatives and the physicians that they called upon throughout the United States, to evidence Celebrex's superior gastrointestinal safety and superiority over ibuprofen and diclofenac. A blue over stamp signified that the article was restricted for use because the study's conclusion was not supported by the data. By April 2003, the Class Study was omitted from training and access to the reprint of the article by representatives was restricted by Pfizer's Product Business Team. But sales managers continued to train the sales force in 2003 and 2004 that the Class Study demonstrated that Celebrex had superior gastrointestinal safety as compared to the older NSAIDs.

142. In 2001 and continuing thereafter until at least some time in 2008, Pfizer directed its sales force to use an article by Dr. Joseph S. Gimbel, *et al.*[8] to claim that Celebrex was superior to Percocet for acute pain, even though the study does not support such a claim. While Pfizer taught its sales representatives that the study was scientifically valid, the study is actually clinically irrelevant because it is based upon a comparison of 200mg of Celebrex 3 times daily for 5 days, which exceeds the FDA-approved dosages for acute pain, with 3 daily doses of Percocet, hydrocodone 10 mg/acetaminophen 1,000 mg. The study is also flawed because it compared Percocet, a short-acting drug, with the longer-acting Celebrex. The Percocet dosage studied is sub-therapeutic because the drug is normally prescribed to be taken 4 times daily and a total of 6 doses may be taken daily. The published article nonetheless falsely represented that the dosage of Percocet studied was

[8] Joseph S. Gimbel, MD., Andrew Brugger, MD., William Zhao, PhD., Kenneth M. Verburg, PhD, and G. Stevens Geis, MD, PhD., entitled Efficacy and Tolerability of Celecoxib versus Hydrocodone/Acetaminophen in the Treatment of Pain After Ambulatory Orthopedic Surgery in Adults, published in *Clinical Therapeutic*; Vol.23, No.2.February, 2001.

the most frequently prescribed by practicing physicians. Pfizer's sales representatives thus perpetuated the misleading comparative results of the Gimbel Study when they detailed the findings with doctors.

143. In 2002, Pfizer (through Pharmacia, its predecessor organization) provided internal training and a training document that claimed Celebrex had superior cardio-renal safety compared to Rofecoxib (Vioxx) and led physicians to falsely believe that Celebrex had superior renal safety. That claim had not been proven by reliable scientific studies.

144. In about April 2002, Pfizer managers provided documents to their Celebrex sales representatives, instructing them to advise physicians that the Vigor-Merck Study on Vioxx showed that Celebrex had the same superior gastrointestinal safety results as Vioxx. But, the Vigor-Merck Study[9] did not involve Celebrex. Thus, the Class Study failed to establish a scientifically valid basis for making superiority claims about Celebrex in comparison to the older NSAIDs.

145. Pfizer's sales force widely distributed a memorandum dated December 11, 2002, from New York Methodist Hospital attending physicians advising that the hospital was removing Vioxx from the hospital formulary on November 27, 2002 and that there was increased legal risk if Vioxx were used. The sales force used this highly influential hospital memorandum with physicians to suggest that Celebrex was safer to prescribe than Vioxx. This memorandum was not approved by Pfizer's Review Committee, was not provided by Pfizer to the FDA as a marketing document, and was not marked in a

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[9] C. Bombardier, L. Laine, A. Reicin, *et al.* Comparison of upper gastrointestinal toxicity of rofecoxib and naproxen in patients with rheumatoid arthritis, published in the *N. Engl. J. Med.* 2000; 343:1520-1528.

way that would alert Pfizer's representatives that it was not to be used for pharmaceutical promotion. Managers copied this document from a slide set being used in a Pfizer speaker program and gave it to the sales representatives.

146. Pfizer District Manager Krams, throughout the summer of 2003, emphasized in training the sales force that Celebrex was superior in efficacy, safety, and tolerability.

147. In March 2004, a Pfizer representative reported that Mrs. Royder, office manager of the Columbus, Ohio, Townstreet Family Practice, was demanding payment in return for maintaining Celebrex and other drugs on the practice's private formulary. After Pfizer representative Brandee Trout proposed paying the clinic to provide multiple preceptorships, District Manager Krams decided that providing a Pfizer grant to the clinic would satisfy the Royders and maintain Pfizer's Celebrex and other drug sales generated by the clinic. In addition, Pfizer sales representative Brandee Trout also started doing preceptorships in the Royders' Townstreet clinic.

148. While Celebrex was not approved for general pre-surgical and post-surgical pain treatment, on or about June 1, 2003 Pfizer's Alta District (Portland, Oregon) distributed to the national sales force examples of physicians' COX-2 protocols or "standing orders" for general surgery and plastic surgery. Managers used these examples to urge sales representatives to obtain such standing orders in their own territories. Sales representatives complied, thus influencing physicians' prescription writing practices for off-label uses.

149. On July 24, 2003 at a training session with Relator's Ohio district sales representatives, a Pfizer hospital representative shared samples of standing physician orders from highly-influential doctors and hospitals, including UMass and SUNY, for general pre-surgical

and post-surgical Celebrex use, which were off-label uses. These documents were not approved by Pfizer's Review Committee, nor were they provided by Pfizer to the FDA as marketing documents. Pfizer sales representatives used these standing orders to improperly influence other physicians to prescribe Celebrex. During the summer of 2003, Pfizer District Manager Krams directed his subordinates to obtain at least one surgical standing order by the end of August.

150. In the summer of 2003, District Manager Krams told his sales force that they should make arrangements for speaker programs that would promote the off-label use of Celebrex for general surgery, with the emphasis on pre-surgical use and obtaining standing orders.

151. On October 6, 2003, a Pfizer sales representative was sent an email by a Pfizer Medical Liaison Specialist that directed her to advise physicians that Celebrex was contraindicated in patients using Sulfonamide due to skin reactions, but suggested that the problem was not as serious as a Sulfonamide allergic reaction. This topic was discussed with sales representatives in an October 15, 2003 sales team meeting led by District Managers Michael Krams and Melissa Cohen without the benefit of any Pfizer scientific liaison personnel present. At the meeting, after reading and discussing the unapproved article, Relator's Cluster sales team members minimized the seriousness of the contraindication and subsequently did the same in the field when promoting Celebrex to physicians.

152. In October 2003, Pfizer's national Training Department for Celebrex provided the sales force with the "Clinical Companion for Celebrex," listing many research articles about Celebrex, including an off-label article that stated that Celebrex was not indicated for post-operative pain. The most important Celebrex gastrointestinal safety study, the Class

Study, which showed no Celebrex superiority in gastrointestinal safety when compared to traditional NSAIDs, was omitted.

153. In the fall of 2003, Pfizer's Training Department sent the Celebrex sales and sales management employees a British research article by T. M. MacDonald *et al.*[10] Using this article, Pfizer's sales force claimed that Celebrex showed superior gastrointestinal safety to the drug Mobic, even though the MacDonald Study was observational only, was aimed at determining whether patients prescribed the newer NSAIDs had higher gastrointestinal risk factors than those prescribed the older NSAIDs, showed higher adverse events for Celebrex than the older NSAIDS, was funded by Pfizer, and did not assess risk factors that could affect results. Dr. MacDonald requested that his research not be used for comparative claims and the article did not meet FDA-required minimum scientific standards for such claims. Nonetheless, Pfizer improperly used it in marketing, including face-to-face physician encounters, for comparative claims.

154. Prior to the Pfizer regional training for its Celebrex representatives on November 21-23, 2003, Pfizer sent approved marketing materials to Relator and its Celebrex sales representatives and supervisory sales managers. These approved Celebrex training materials came from the national Pfizer Celebrex Business team and claimed that Celebrex and Bextra offered doctors "a COX-2 portfolio of … proven efficacy with superior GI safety…"

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[10] T.M. MacDonald, et al, Channeling Bias for the Incidence of Gastrointestinal Hemorrhage in Users of Meloxicam, Coxib's, and Older Non-Specific Anti-inflammatory Drugs, *GUT* (2003) (Celebrex reprint Order # CL 154618).

155. During the November 2003 regional meeting that Relator attended, Pfizer's training relied upon selective portions of several scientific articles and omitted highly important portions of those same articles. Pfizer failed to disclose to its sales staff and, ultimately, to physicians to whom the sales force marketed Celebrex and Bextra, that dosages recited in the articles exceeded FDA-approved levels, that claims of Celebrex's superior gastrointestinal safety and cardiac safety over competitor drugs was not established, and that Celebrex was not proven safe and effective for general pre-operative and post-operative surgical use.

156. On November 19, 2003, at the regional Pfizer sales training meeting, the "Chunnel Agreement" was presented that contained the unauthorized and untrue message that Celebrex is superior to NSAIDs for relieving pain, that it is superior to NSAIDs in terms of cardiovascular safety, that it is ideal for long term care patients with chronic pain, and that it is appropriate for general pre-surgical and post-surgical pain relief.

157. At the November 19-21, 2003 Pfizer training, District Manager Krams and other managers of multiple divisions urged sales representatives to represent to physicians that only Vioxx had serious cardiovascular problems, not Celebrex. These directives were known to other Pfizer management officials, including Regional Director Steve Reese.

158. In December 2003 and continuing thereafter, Relator and other Pfizer sales representatives were directed to target obstetricians, gynecologists, and anesthesiologists to obtain protocols or "standing orders" for Celebrex for pre-operative and post-operative surgical use.

159. On May 27, 2004, at Relator's regional Pfizer sales meeting that he attended, all representatives and managers were required to participate in compliance training and sign

a document that they would promote Pfizer products in accordance with their compliance training. During the training sessions, managers reviewed representatives' sales "detail" binders and removed unapproved sales materials, but took no action against offending representatives. Nonetheless, District Manager Krams continued to insist that representatives should promote Celebrex by saying it has superior efficacy to naproxen. He also insisted on the continued use of a document about cardiovascular safety that included the Solomon Study and which was provided by Pfizer's Medical and Drug Information unit.

160. In Relator's "Cluster Meeting" on July 28, 2004, sales representatives were trained to emphasize Celebrex's superior efficacy and off-label use for pre-operative and post-operative surgical use and chronic pain management, as outlined in the "Chunnel Agreement."

161. In a September 1, 2004, training with Pam Robertson, Assistant to Relator's Pfizer Regional Director, she criticized Relator for not promoting Celebrex to physicians as having superior efficacy to older NSAIDs.

162. In order to promote Celebrex, in 2004, Ohio sales representatives were encouraged to tell physicians that the Ohio Medicaid decision to include Celebrex on its approved drug formulary proved its superior efficacy and safety over Vioxx, even though the Pfizer sales force had no knowledge of why it was placed on the formulary list.

163. In October 2004, with Vioxx removed from the market due to cardiac safety concerns, Celebrex sales significantly decreased. In response, Pfizer's national sales department issued a promotional piece to be used by its sales force that falsely claimed that Celebrex had shown superior gastrointestinal safety, even at doses above FDA-approved levels,

superior efficacy, and no increased risk of adverse cardiac events. However, on October 14, 2004, in a nationally sponsored teleconference reviewing the White cardiovascular study which Relator attended by telephone, Dr. White stated that there was no difference in efficacy between Celebrex and the older NSAIDs.[11] On the same day, Relator and all other Celebrex sales representatives received a message from Pfizer Cluster employee Clair Collins, who worked in a Pfizer regional or national sales office, stating that Mobic has "significantly more GI risk than Celebrex." This "selling point" was not supported by reliable scientific research.

164. In April 2003, a high-prescribing medical practice with a large volume of Medicare and Medicaid patients, the Townstreet Family Practice in Columbus, Ohio, solicited a $7,500 grant from a Pfizer sales representative in exchange for Townstreet maintaining Celebrex and other drugs on its private drug formulary. Dr. Royder, the owner, prescribed approximately 200 prescriptions monthly for Celebrex, prior to losing his medical license for violating laws relating to prescriptions.

165. In the fall of 2003 and continuing thereafter, Celebrex samples were in short supply in Ohio and likely nationwide. District Manager Krams instructed Relator and his coworkers to open Pfizer sample packages and distribute smaller quantities to the complaining physicians. In mid-September 2004, Relator notified Pfizer District Manager Krams that breaking Celebrex samples into smaller packages was unlawful, since there was only one

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[11] Dr. White co-authored the "White Study" or "White Article" by William B. White, MD, Gerald Faich, MD, Andrew Whelton, MD, Clement Maurath, MS, Nancay J. Ridge, MD, Kenneth M. Vergurg, PhD, G. Steven Geis, MD, PhD, and James B. Leftkowith, MD, entitled Comparison of Thromboembolic Events in Patients Treated with Celecoxib, a Cyclooxygenause-2 Specific Inhibitor versus Ibuprofen and Diclofenac, published in the *American Journal of Cardiology*, Feb. 15, 2002.

approved package insert and many of the packages would not have package inserts. Mr. Krams advised Relator that a Pfizer regional compliance official had approved the activity.

D. Relpax

166. Eletriptan hydrobromide, a prescription drug manufactured and marketed by Pfizer under the brand name "Relpax," was FDA-approved for treatment of acute migraine headaches in December 2002.

1. False Marketing of Relpax as Superior: Using Off-Label and Unapproved Research

167. There is no claim of Relpax superior efficacy over other competitor drugs in the FDA-approved label for Relpax and has never been such a claim in the label. Nonetheless, Pfizer directed its sales force to claim that scientific data established Relpax's superiority over competitor migraine medications.

168. At a May 2003 national training session in Detroit, Pfizer presented its Relpax sales force present at the training with a visual presentation about Relpax. The presentation discussed other competitor drugs to Relpax. There was no discussion in the presentation of any test results showing that Relpax was superior to Imitrex (sumatriptan) or other competitor drugs. The presentation contradicted Pfizer's management's repeated and persistent oral and written claims of Relpax superiority to Imitrex.

169. Pfizer's Relpax marketing strategy involved extensive use of published research studies, particularly two articles authored by Sandrini[12] and Mathew,[13] to claim that Relpax was

[12] G. Sandrini, M. Farkkila, G. Burgess, E. Foster, Haughie for Eletriptan steering committee, Eletriptan vs. Sumatriptan: A Double-Blind, Placebo-Controlled, Multiple Attack Study, published in *Neurology* 2002; 59:1210-1217.

superior to its competitor, Imitrex. Because the two Studies' conclusions about superiority had various deficiencies as to scientific method and/or analysis and involved claims of superiority that were not in the label, use of the Sandrini and Mathew Studies for comparing Relpax more favorably to Imitrex was off-label marketing and misbranding.

170. Pfizer's Relpax Business Team marked the Sandrini Article as not to be used for promotion in the field. Nonetheless, Pfizer's sales managers directed representatives to use reprints of the off-label Sandrini Article directly with physicians.

171. The FDA investigator's report of August 5, 1999[14] examined the Sandrini and Goadsby[15] Studies as part of the Relpax application for FDA approval. Authored by Randy Levine, M.D., the FDA report rejected comparative claims that Pfizer proposed as a result of the studies. Among the FDA report comments are:

* The evidence was not suggestive of a difference between 40 mg [of Relpax] and sumitriptan.
* The efficacy of the drug was not shown to be better than sumitriptan at doses with a similar adverse event profile.
* It does not appear to offer any advantages over approved 5HT1 agonists [triptans].
* Comparative trials with sumitriptan did not demonstrate a clear superiority and risk to benefit ratio.

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[13] Ninan T. Mathew, M.D.; Jeam Schoenen, M.D.; Paul Winner, D.O.; Nancy Muirhead, M.S.; Carolyn R. Sikes, Ph.D., Comparative Efficacy of Eletriptan 40mg Versus Sumatriptan 100mg, published in *Headache* 2003; 43:214-222.

[14] Levin, Randy, M.D., Neurology Team Leader, FDA Division of Neuropharmacological Drug Products, August 5, 1999, Subject: NDA 2016, Relpax (eleptriptan).

[15] P.J. Goadsby, Ferrari M.D., J. Olesen, Eletriptan in acute migraine: a double-blind, placebo-controlled comparison to sumatriptan, *Neurology* 2000.

* The studies did not provide adequate evidence that the drug was superior to sumitriptan.

The Sandrini Study was off-label, since it researched and discussed an initial Relpax dose of 80mg, which is twice the FDA-approved initial dose.

172. Another FDA researcher questioned the Mathew Study findings, including commenting that the research was not adequately controlled to be scientifically reliable. The Mathew Study failed to eliminate certain study participants who previously used Imitrex.

173. The Relpax label, as approved by the FDA, refers to the parts of the Sandrini and Goadsby Studies that compared Relpax to placebo. The Relpax label does not mention Relpax treatment compared to Imitrex treatment. That is, the comparative results of the Sandrini Study (identified with the FDA as # 318) and the Goadsby Study (identified with the FDA as # 314), which involved Imitrex, are not mentioned in the FDA-approved package insert. The Mathew Study results are not included in the label in any fashion. Without the Mathew Study and the Sandrini and Goadsby comparative results to Imitrex being in the label, Pfizer had no basis for marketing claims that Relpax was superior in efficacy to Imitrex.

174. Prior to the national training meeting in May 2003, in Detroit, Michigan, Pfizer's training materials directed the entire Relpax sales force, including Relator, to promote Relpax by making false comparative claims of superiority to Imitrex. Pfizer's training materials were aimed at causing sales representatives to conclude that Relpax provided superior migraine pain relief when compared with Imitrex, at 2 hours after administration, even though the FDA had not permitted such comparative claims. The superiority claims were based on studies by Dr. Sandrini and Dr. Mathew.

175. In November 2003, Pfizer distributed to its Relpax sales force a CD-rom that directed sales representatives to make false statements about Relpax's superior efficacy. The CD misrepresented study data from the Sandrini and Mathew studies and used the term "superior" to compare Relpax's efficacy with 100mg of sumatriptan (Imitrex). The sales presentation to be made by the Pfizer sales representatives was to include the message "Relpax is superior from start." The CD instructed sales representatives to tell physicians that Relpax's superior efficacy was in the label. The CD stated that Relpax's efficacy "appears in the U.S. label" and is "shown in the U.S. label." However, the comparative data claims are not in the label and the FDA investigators did not find that the superiority claims were adequately demonstrated by the research submitted.

176. During training sessions conducted November 19, 2003 to November 21, 2003, District Manager Krams trained sales representatives under his supervision to use Pfizer Medical and Drug Information proactively to show the superiority of Relpax over another competitor drug, Zomig. The Medical and Drug Information involved the efficacy of the Zomig nose spray and was marked by Pfizer as "Not to be printed, reproduced, left behind or used in detailing." Both District Manager Krams and Regional Director Steve Reese told sales representatives to use the document to promote Relpax as having a more effective response, significantly less recurrences of headaches, and significantly less use of alternative "rescue" medications, even though there was no FDA-approved basis for making such comparative claims of superiority over Zomig.

177. In November 2003, Pfizer provided its Relpax sales representatives with a Relpax Plan of Attack Resources Guide that guided the representatives in ordering materials to be used to promote false claims of Relpax superiority to other competitor drugs.

178. At the November 2003 regional training meeting, Pfizer's Regional Management Team trained Relpax sales representatives on 3 key clinical studies by Drs. Sandrini, Mathew, and Farkkila[16] *et al.*, that Pfizer falsely claimed were proof that Relpax was superior to Imitrex in providing migraine pain relief. Though reviewed by the FDA, none of the superiority claims to competitor drugs were included in the FDA label. Further, the Sandrini Article is based upon a dose not approved by the FDA and was marked off-label by Pfizer; the Mathew Study was rejected by the FDA's investigator due to inadequate controls; and the Farkkila Study was not a comparative study and was marked off-label by Pfizer's Review Committee.

179. In May 2004, to bolster its claims of Relpax superiority to Imitrex, Pfizer Regional Director Reese utilized a research article authored by Hans-Christoph Denier *et. al.*[17] The Denier Article was not independent scientific research, but was merely a summary of data from the flawed Sandrini, Mathew, and Goadsby Studies. The Denier study combined primary and secondary endpoint data and contradicted the package insert that stated:

> Comparisons of the performance of different drugs based on results obtained in different clinical trials is never reliable. Because studies are generally conducted at different times, with differing patient samples, investigators, criteria, and interpretations of the same criteria and under different conditions (dose, dosing regimen, etc.), quantitative estimates of treatment responses and response timing maybe expected to vary considerably among studies . . . .

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[16] Markus Farkkila, J. Olesen, C. Daholf, M.D., L. J. Stovner, J. P. Bruggen, S. Rasmussen, N. Muirhead, C. Sikes, Eletriptan for the treatment of migraine in patients with previous poor response or tolerance to oral sumatriptan, *Cephalalgia* 2003, 23, 413-471.

[17] Hans-Christoph Diener, Robert Ryan, Wei Sun, Jayasena Hettiarachchi, The 40mg. Dose of Eletriptan: Comparative Efficacy and Tolerability Versus Sumatriptan 100mg, published in *European Journal of Neurology* 2004, 11:125-134.

Nonetheless, Mr. Reese insisted that the Denier Article conclusively established that Relpax was the only drug in the entire class of "triptan" drugs that was consistently superior to Imitrex.

180. In a May 2004 sales training session, Regional Director Reese, in a presentation to his subordinates that relied upon the Denier Article, declared that Relpax was superior and that the FDA had approved such comparative claims. District Manager Krams made similar claims of Relpax superiority and stated that the superiority claim had received FDA approval.

2. Relpax Switching Efforts

181. Pfizer sales representatives followed management directives and used various off-label and unapproved research articles in direct marketing to physicians in a Pfizer-approved "upgrade campaign" to switch patients from Imitrex to the newer Relpax.

182. Claiming superiority to Imitrex, Regional Director Reese, District Manager Krams, and other Pfizer managers in or about August 2003 engineered sales activities to switch patients from existing drugs to the allegedly "superior" Relpax. Representatives were instructed to ask physicians' office staffs to compile lists of patients who had been treated for migraines. This often required Pfizer or the representative providing compensation to the physician's office for the work required to identify patients treated for migraines. The representative requested the information on patients who experienced migraines in order to solicit the patients to come to the physician's office for new "superior" migraine treatment--with Relpax. With the assistance of the Pfizer representative, or by the Pfizer representative entirely, each such identified patient was sent a letter encouraging a doctor's office visit to discuss a new migraine treatment.

183. In 2004, Pfizer District Manager Krams directed sales representatives to obtain multiple Relpax coupons for free prescription from Pfizer's website. To accomplish this, sales representatives had to enter the names of patients, usually fake names fabricated by the representatives, to get the coupons. The coupon paid for the entire prescription. Then, as directed by District Manager Krams, the representatives called upon physician offices with high numbers of Medicaid patients and asked them to switch these patients to the "superior" Relpax. This was done in anticipation of the Ohio Medicaid formulary adding Relpax, so that patients using the coupon for their first Relpax prescriptions would thereafter obtain Relpax refills.

184. In or about June 2004, in order to switch patients to Relpax using false claims of superiority, Regional Manager Reese established competitions among the representatives to achieve the highest number of doctor office "switch campaigns." Mr. Reese urged each representative to conduct 20 or more such letter-writing campaigns each quarter. This effort was conducted in multiple regions and was highly successful in increasing the number of Relpax prescriptions.

185. Relator's final notes of his Pfizer regional training on November 19-21, 2003 also document a "switch campaign" by using the Farkkila Study. Relator gave these final notes to Relator's District Manager and Regional Manager. Relator's final notes were a combination of his own meeting notes, taken during the training, and those meeting notes that another representative authored and that Mr. Krams had approved. In the combined form, Relator's final meeting notes accurately reflect that the representatives were directed to advise physicians that the Farkkila Study showed that Relpax had high efficacy in a patient population that had failed to respond to Imitrex. However, the

Farkkila Study actually stated the Study had a limitation because "the historical report of sumatriptan treatment failure was not confirmed by prospective treatment." The Study authors also pointed out that there was a "limitation" in the Study due to the "lack of a sumatriptan control group." According to the Farkkila Study's authors, if such an active Imitrex control group had been included and if the Relpax group showed statistically significant better results as compared to the Imitrex control group, the Study results would have been much more useful. Thus, the Farkkila Study's conclusions are very limited and could be true for virtually any drug in the class.

186. On January 28, 2004, District Manager Krams directed Relator to post homemade "wellness check" forms in physician's offices. The "wellness check" asked patients 3 questions about their migraines. If the patient answered positively to any question, the patient was instructed to ask the physician about a new migraine medication.

187. Pfizer's efforts to switch patients to Relpax caused thousands of patients to visit their physicians under false pretenses and to obtain a prescription for a "superior" drug, which in fact was not proven superior to existing migraine medications.

3. Relpax Kickback Marketing Schemes Promote Switching to Relpax

188. Beginning in the summer of 2003 and continuing through October 2004, Pfizer implemented a policy and practice of encouraging physicians to prescribe Relpax and patients to fill Relpax prescriptions, thereby increasing Pfizer's prescription drug market share and profits.

189. Pfizer used a purported clinical study scheme to generate Relpax sales involving the "Multiple Migraine Outcomes Study." Pfizer representatives provided physicians with patient literature and free Relpax samples, called "Challenge Kits." Physicians were told

that they were participating in a clinical study and that it was urgent to have their patients use Relpax to participate. Pfizer sales representatives distributed samples that were not in appropriate FDA-approved, Pfizer-issued, labeled sample packages. Instead, Pfizer sales representatives, at the direction of their managers, relabeled samples and placed them in plastic bags issued by Pfizer's Relpax Product Business Team. Included on the outside of the bag was a Relpax prescription sticker that physicians could remove to affix to their own prescription pads. In order to "complete" the study, a patient had to fill the prescription and answer some questions. In return for filling the prescriptions and answering the questions, the patient received a "gift" from Pfizer's product business team. Pfizer District Manager Krams admitted that the purpose of this "study" was to increase Relpax prescriptions.

190. Well after Relpax's FDA approval, Pfizer's Relpax Business Team selected high-volume Medicaid prescribers throughout the nation to participate in a "study" where the physicians were paid large sums of money to place 3 patients on Relpax and compare the results with patients given placebos. One such physician was located on West Broad Street in Columbus, Ohio. The research representative of the independent research company Pfizer hired to conduct the "study" reported to Relator that it was a national program and that there were multiple test sites in Ohio and elsewhere that used high-prescribing physicians with only a few patients per site. These facts indicated to Relator that the study was nothing more than a method to pay doctors who were high migraine-medication prescribers to gain experience using Relpax.

191. As part of its Relpax promotion activities, by June 2003, Pfizer instigated a speakers bureau program for physicians. Doctors were paid to travel to a free weekend "speakers"

training session in a metropolitan hotel. Some speakers thus trained were never used as speakers, nor did Pfizer ever intend them to make presentations on its behalf because they did not have the knowledge, professional status, or presentation skills to be speakers. In many instances, the purpose of Pfizer's Relpax speakers bureau was not to recruit Relpax lecturers, but was primarily to influence the speaker's own prescribing habits.

192. District Manager Krams encouraged Relator and other sales representatives to recruit speakers on Relpax so that the speakers would write more Pfizer drug prescriptions, particularly Relpax. District Manager Krams directed one of his sales representatives to recruit Dr. Frank DiBenedetto, D.O. as a speaker and attend the Pfizer out-of-town expense-paid "speaker training," without regard to his speaking ability or migraine expertise. Pfizer recruited Dr. DiBenedetto because he had a large Columbus, Ohio Medicaid patient practice and wrote a large number of migraine medication prescriptions. The speakers bureau recruitment was successful as Dr. DiBennedetto thereafter was more receptive to Relator's sales calls about Relpax and other Pfizer drugs.

193. On November 25, 2003, Pfizer provided prescription sales data to its sales force showing that the Columbus, Ohio Townstreet Clinic operated by the Royder family was responsible for writing about 80 Relpax prescriptions monthly. This Clinic was Pfizer's top Relpax prescriber in Relator's sales territory and assisted Relator in being highly ranked for Relpax sales nationally. Dr. Palma, who worked at the Royder clinic, told Relator that his prescription practices were dictated by a "private formulary." Various Pfizer sales representatives and other pharmacy company sales representatives told Relator that kickbacks to Mrs. Royder and/or the Townstreet Clinic were made to ensure listings on the lucrative Townstreet formulary.

194. Pfizer also used a program to pay physicians $250 each, ostensibly to educate Pfizer sales representatives about Relpax on conference calls. In reality, the payment was a transparently disguised kickback designed to convince the physician to prescribe the drug. The physicians were selected by sales representatives based on the volume of their practices and the potential for increased prescriptions of Relpax. Pursuant to this program, Pfizer sales representatives were repeatedly "educated" on the very same clinical studies, including unapproved and off-label studies, by various physicians. The sales representatives participating in these conference calls were instructed to pretend that the physician was presenting new material to them and to ask questions as if they were hearing the information for the first time. On several of these fake "educational briefings" in which Relator participated, the speaker failed to give any organized presentation at all, but thanked Pfizer for the opportunity to participate in the program. Pfizer instructed sales representatives to contact physicians a few days after their so-called "educational briefings" to inquire whether the physicians prescribed more Relpax after giving their presentations.

195. Pfizer began paying physicians according to the scheme outlined above in January 2004. Relator personally participated in about 10 of these fake conference calls and believes there were others between January and June 2004. When Relator asked District Manager Krams to discontinue the calls, Mr. Krams replied that "the whole region was doing them" and therefore they were unlikely to be sanctioned for the practice.

196. Relator reported these fake "training" conference calls on April 1, 2004 by e-mail to Andrew Powell, Pfizer's Regional Great Lakes' Human Resources Director, who assured Relator that he would inform Pfizer's Compliance department. Relator provided

information about the false training sessions and improper payments to physicians to Pfizer's Compliance employees on April 17, 2004, in Columbus, Ohio.

197. Still another program of unlawful kickbacks began in the summer of 2003 and continued through October 2004. Under this program, Pfizer recruited various physician specialists to accompany Pfizer sales representatives to particular family medical practices or general practitioner offices, with the hope of gaining more referrals from these practitioners. To accommodate these physician specialists and increase Relpax prescriptions written by these specialists, Pfizer organized another sham education program whereby these physician specialists were paid $500 to $750 per visit to accompany representatives on sales calls and deliver educational presentations to the family or general practitioners' offices. These "educational presentations" were, however, thinly-veiled introductory and matchmaking services provided by Pfizer to the physician specialists in exchange for increased Relpax prescriptions.

198. A senior Pfizer representative informed Relator that, although he did not participate in this presentation program himself, these educational presentations were common in Pfizer's Cluster X, the other half of Pfizer's sales force. Indeed even after an internal company memorandum was written and circulated within Pfizer directing that these activities be terminated, Relator was aware of ongoing violations with the use of the speakers programs through December 2006.

199. Relator informed District Manager Krams, on or about October 18, 2004, that arranging paid educational presentations was illegal and in violation of Pfizer's compliance rules because they amounted to a service provided free of charge (indeed, with an honorarium) to these physicians in exchange for business, which violated federal anti-kickback laws.

Immediately after making this report, Relator went on vacation and thereafter Pfizer ordered him not to return to work

200. By conducting sham educational presentations about Relpax and providing remuneration and services to presenting physicians and patients in order to secure future prescriptions and orders for the drug, Pfizer violated the Anti-Kickback Statute and the Stark Law.

201. By extending illegal kickbacks to physicians which are not disclosed to the federal government in violation of 42 U.S.C. § 1320a-7b(b), the "Anti-Kickback Statute," Pfizer caused and/or induced physicians and other healthcare professionals who sought reimbursement for Relpax from federal and state government-funded health programs to file false or fraudulent certifications regarding compliance with the foregoing statutes in violation of the False Claims Act and relevant state laws.

202. On every occasion in which Pfizer induced a physician or other health care professional to prescribe Relpax through means of improper kickbacks and who later sought reimbursement for prescriptions of the drug from federal government-funded health programs, a false claim was submitted in violation of the False Claims Act.

4. Unsolicited Medical and Drug Information

203. At Pfizer's August 27, 2003, District mid-year Plan of Attack meeting, District Manager Krams told the Pfizer sales representatives to use Medical and Drug Information for marketing Relpax, in violation of FDA law and the Pfizer Corporate Integrity Agreement resulting from its off-label marketing of Neurotin. Regional Director Reese announced that Pfizer researchers were publishing clinical papers comparing Relpax with competitor drugs, including Amerge, Zomig, and Maxalt, as well as a Relpax cardiovascular study. Some of these studies did not in fact exist. Sales representatives were directed to send

Pfizer Medical and Drug Information to physicians without obtaining physician requests for the information, in order to expand the use of Relpax.

204. During the summer of 2004, in an effort to boost Relpax sales, Pfizer Representative Brandee Trout, who remains employed with Pfizer, sent packages of scientific research articles about Relpax to physician's offices, which were marked by Pfizer as "Do not show to physicians." Relator and others reported this conduct and management's failure to take action about it to Pfizer's compliance and human relations department.

E. Lyrica

205. Pregabalin, a prescription drug used to treat nerve pain and epilepsy, developed and marketed by Pfizer under the brand name "Lyrica," received FDA approval on December 31, 2004, for the treatment of pain associated with Diabetic Peripheral Neuropathy (a complication of diabetes) and Postherapeutic Neuralgia (persistent pain after shingles). On June 13, 2005, the FDA approved Lyrica for the treatment of partial onset seizures in adults with epilepsy. More recently, on June 21, 2007, Lyrica was approved for the management of fibromyalga. Prior to December 31, 2004, Lyrica was not FDA-approved for any use.

206. At least one senior Pfizer sales representative, Brandee Trout, falsified physician and pharmacist requests for medical information through Pfizer's Medical and Drug Information unit about Lyrica's uses and efficacy months before the drug was approved by the FDA. Ms. Trout's records, disclosed to the FDA, list 11 requests for information on Lyrica supposedly made by physicians and pharmacists as early as September 2004 and continuing through November 2004, 2 to 4 months before the FDA first approved Lyrica for use.

207. Relator telephoned, or spoke in person to, several individuals listed in Ms. Trout's files, including pharmacist David Byrd, R.Ph., Kevin Olson, D.O., Kevin Lake, D.O., and Glenn Iben, M.D. Relator learned that none of the pharmacists or physicians he spoke to had requested information about the drug. Ms. Trout's notes specify, for example, that Dr. Iben requested information on an article he had read about Lyrica. However, neither Dr. Iben nor David Byrd R.Ph., were even familiar with the generic name pregabalin or the brand name Lyrica. Nonetheless, Pfizer's Medical and Drug Information Unit sent Dr. Iben, Pharmacist Byrd, and the other physicians and pharmacists on Ms. Trout's list, unsolicited marketing materials and studies about Lyrica prior to its approval by the FDA.

208. In addition, in September 2004, Pfizer's Medical and Drug Information Unit responded to Ms. Trout's falsified requests for drug information by sending information to several doctors regarding the use of Lyrica for pain management, despite the fact that the drug had not been approved by the FDA for any purpose and that pain efficacy was not even within the parameters of the yet-to-be approved package insert for Lyrica. For example, information on pain efficacy was sent to physician Wes Hard, M.D. When Relator later contacted Dr. Hard in the fall of 2004, Dr. Hard stated he had never heard of pregabalin or Lyrica.

209. The use of medical and drug information to proactively market drugs was part of Pfizer's routine training of sales representatives. On November 19, 2003, Relator and other sales representatives from at least six sales districts attended a training conducted by Pfizer managers, in which the representatives were instructed on how to proactively promote drugs using Pfizer Medical and Drug Information documents. Pfizer Medical and Drug Information documents were supposed to be used only by physicians who specifically

requested scientific materials or information. The contents of Medical and Drug Information documents were not to be detailed by sales representatives in face-to-face presentations to doctors.

210. In late May 2004, Relator and other sales representatives and managers attended a compliance training conducted by upper level management in which they were instructed about potential legal consequences of the prohibited Pfizer use of Medical and Drug Information to proactively market drugs. Nonetheless, within months of this training, Ms. Trout began fabricating requests for Medical and Drug Information regarding Lyrica, deliberately and actively marketing an unapproved drug to physicians and pharmacists in violation of FDA regulations and Pfizer's own compliance manual regarding unsolicited requests for Medical and Drug Information.

211. In November 2004, Relator reported Ms. Trout's unlawful marketing to Pfizer's Compliance department. To Relator's knowledge, no disciplinary action was taken against Ms. Trout and Pfizer did not issue any statement or provide any training to address this pre-approval marketing of Lyrica. Ms. Trout's unlawful marketing, as well as Pfizer's failure to respond or report the incident to the Office of the Inspector General, violated FDA regulations and Pfizer's Corporate Integrity Agreement.

212. As of March 2006, Pfizer's Sales Representatives were using the Lyrica speakers' program to invite physicians to be speakers for Pfizer training programs. The speakers were chosen based upon their potential to be high prescribers of Lyrica, such as physicians with large numbers of Medicaid patients, not upon their expertise or standing in the medical community. This marketing and kickback activity resulted in false claims being submitted to the government for payment.

F. Depo-Provera

213. Medroxyprogesterone, an injectable liquid contraceptive that Pfizer manufactures and markets under the brand name "Depo-Provera," was approved by the FDA on October 29, 1992 for use as a contraceptive to prevent pregnancy.

214. The Depo-Provera contraceptive injection is typically administered by a physician, physician's assistant, or registered nurse once every 3 months. Each vial of liquid contains one 3-month dose. Depo-Provera was covered for most patients under Medicaid.

215. For years, Pharmacia, Pfizer's predecessor, trained and encouraged its district managers and sales representatives to "do deals" and "barter" with physicians and medical institutions by offering large quantities of drug samples (what Pfizer now calls "starters") in exchange for large or standing orders for those or other drugs. In some deals, physicians paid for 100 to 300 units of Depo-Provera and received 25 to 75 free units of Depo-Provera valued at $1250 to $3750. This bartering occurred in multiple states. In the end, managers and representatives were striking deals with state Medicaid departments to get much larger purchases and thereby dramatically increase their bonuses.

216. In conducting "deals" of samples for orders, sales representatives encouraged physicians to bill Medicaid and other agencies for reimbursement of the full reported, reimbursable price of Depo-Provera even though the physicians paid nothing for the drug. Each claim for reimbursement of a dose dispensed as a sample constitutes a violation of the False Claims Act. Such bartering also illegally manipulated federal and state Medicaid "best price" and "average manufacturer's price" reimbursement and rebate calculations because the company's improper use of samples to conduct deals drastically decreased the average price per dose paid by the selected physicians and state Medicaid departments, while

Medicaid reimbursed these physicians at an artificially higher rate. This practice also improperly influenced physicians' decisions about whether to prescribe Depo-Provera and patients receiving those drugs cannot be certain that their treatment was guided solely by their physicians' medical assessment of their diagnoses.

217. During a Pfizer sales meeting held in or around August 1998, Pfizer sales representatives revealed that they were engaging in "deals," whereby the representatives provided physicians with free samples of Depo-Provera in exchange for large and standing orders of Depo-Provera or other drugs.

218. At this time, Relator informed his Pfizer District Manager, Gary Grote, of the deals and specifically quoted the applicable passages of company compliance manuals of Pharmacia, Pfizer's predecessor, expressly prohibiting such practices. At Mr. Grote's instruction, Relator gave a presentation the next day on a conference call with all sales representatives in the district, in which he informed them that soliciting business or otherwise engaging in such deals using free samples was improper. Mr. Grote ended the call by announcing that the inappropriate use of samples would lead to termination of employment. Very shortly after this call, Mr. Grote was promoted to a position in corporate contracting and David Musci became Relator's District Manager.

219. In the weeks following the conference call, a Pfizer sales representative from another district, under the supervision of District Manager Tim DeLeo, sent Relator a "deal sheet," a written agreement promising physicians and pharmacists free samples of Depo-Provera in exchange for large or standing orders of Depo-Provera. The representative explained to Relator that the "deal sheet" was a model for many similar agreements that sales representatives were using throughout the district. She expressed concern that such

bartering may be illegal and asked Relator for advice. Relator replied that such deals did indeed violate federal law and advised her not to complete any more such deals. Relator reported this conduct to Mr. Musci. In about 1999-2000, Relator reported to Mr.Musci that Tim DeLeo's district was using the "deal sheets" to make deals.

220. In the Spring of 1999, Relator received several telephone calls from sales representatives in Kentucky, who stated that their District Manager, Naomi Paziorko of Louisville, Kentucky, encouraged them to provide samples in exchange for sales. Specifically, these representatives promised physicians 3 free doses of Depo-Provera for every 3 orders of the prescription drug Estring. Relator informed these representatives that such deals were illegal.

221. On the day after the conversations with the Louisville, Kentucky area representatives about inappropriate Depo-Provera deals, Relator received a call from that District Manager, Ms. Paziorko, in which she ordered him to stop interfering with her sales representatives. Relator quoted to her the compliance manual provisions stating that these kinds of dealings were illegal, to which Ms. Paziorko repeated that Relator was to stop talking to her sales representatives. Ms. Paziorko told representatives not to talk to him. To Relator's knowledge, Pfizer took no action to stop these improper deals and the unlawful sampling practice continued.

222. Pfizer's continued use of "deals" to sell Depo-Provera was evidenced when, several months later in 1999, Jeff Sampson, a senior sales representative in Kentucky who later became a district manager in Indiana, commented on Relator's sales of Estring. Mr. Sampson accused Relator of doing sample deals with Depo-Provera to sell Estring.

223. Pfizer's deals with Depo-Provera samples was a nationwide scheme that expanded far beyond the Estring deals initially used. In the fall of 1999, Relator spoke by telephone to a senior sales representative in Portland, Oregon who reported that district representatives in Oregon were engaging in similar schemes of sample dealing in order to make their sales quotas, including frequently giving up to 50 samples or more to induce large purchases, very similar to the trades in Relator's region.

224. The bartering and dealing practices continued in Relator's own sales district even after Relator was directed to conduct a conference call presentation to his district sales representatives advising them about the impropriety of doing these deals. In the Fall of 1999, a sales representative in Relator's district informed Relator that he had to continue doing the Depo-Provera deals "in order to keep my numbers up." After this sales representative left Pfizer, Mr. Musci informed Relator that as District Manager, Mr. Musci felt compelled to "honor" a large deal that had been arranged before the sales representative had left the company and accordingly delivered 65 free sample vials of Depo-Provera to a heavily prescribing doctor's office in Dayton, Ohio.

225. A female Pfizer sales representative from Dayton, Ohio, informed Relator that she was managing the former sales representative's accounts and that several accounts demanded sampling deals in order to make purchases of Depo-Provera because, as these offices explained, that is the way they did business with prior representatives. At least two doctors' offices discontinued their business with the Dayton sales representative and denied her any further access to their offices when she refused to continue making Depo-Provera deals using "free" samples.

226. Rather than prohibit the ongoing Depo-Provera "deals" within the region, Pfizer management encouraged and thereby perpetuated these schemes by training newer representatives to conduct deals with Depo-Provera. For example, in the Fall of 1999, Relator contacted a sales representative based in Lancaster, Ohio, who reported that his District Manager, Gregory Clark, was training representatives in his district to make deals with Depo-Provera samples to obtain large orders of Depo-Provera.

227. Relator reported the Depo-Provera dealing as violations of company policy and federal law to his superior, David Musci, on at least two separate occasions during the fall of 1999 and the beginning of 2000, but received no response from management. Pfizer sales representatives told Relator that when they asked their district managers about the illegality of the deals, the managers responded that they needed to do whatever was necessary to get Depo-Provera business.

228. When Relator became aware that sample dealing was a widespread problem, he contacted the company's product manager for Depo-Provera. The Pfizer product manager sent a letter to representatives instructing them to stop bartering samples. Nonetheless the representatives continued to deal in Depo-Provera samples.

229. In 2001, without formal explanation from management, the number of Depo-Provera samples provided to Relator was dramatically reduced. Relator believes samples were diverted to managers and representatives with large state family planning accounts in Indiana, Kentucky, West Virginia, and Ohio.

230. Based on the various reports Relator received from his and other districts within his region and based on the company's nationwide response, dealing in Depo-Provera samples was a widespread practice beginning in 1997. The dealing of Depo-Provera did

not end until April 15, 2003, the effective date of the Pfizer purchase of Pharmacia. Only at that point did Pfizer take steps to end the sales of Depo-Provera to physicians through the Pfizer sales representatives and managers.

231. The prevalence and volume of deals involving free doses of Depo-Provera artificially depressed the price of that drug for the physicians and pharmacists involved and thereby rendered false and misleading the company's representations to Medicaid of the "best price" and "average manufacturer's price" for Depo-Provera in violation of the Medicaid Rebate Statute. The submission of false "best price" data resulted in excessive rebates being paid to the company and to physicians purchasing the drug, thereby violating the False Claims Act.

232. On every occasion in which a physician received free sample doses of Depo-Provera from the company and later sought reimbursement from federal or state government-funded health care programs for Depo-Provera, or drugs purchased pursuant to a deal for Depo-Provera, the company knew or recklessly disregarded that a false claim was being submitted and, therefore, caused that false claim to be submitted, and is itself liable for such false claim.

233. Pfizer concealed this unlawful conduct by, among other actions, failing to disclose that it was engaged in illegal off-label marketing and the payment of kickbacks to physicians and failing to take appropriate actions when Relator made Pfizer's management and compliance officers aware of the violations described in this Complaint. Relator's reporting of these events should have triggered multiple disclosures to the United States under Pfizer's various agreements, including its 2004 Corporate Integrity Agreement with

the Inspector General of the U.S. Department of Health and Human Services to disclose potential False Claims Act and Pfizer pharmaceutical marketing violations.

G. Geodon

234. Geodon (ziprasidone hydorchloride) is an atypical antipsychotic drug approved by the FDA on February 5, 2001 for the treatment of schizophrenia. On August 19, 2004, the label was expanded to include acute manic or mixed episodes associated with bipolar disorder, with or without psychotic features, and acute agitation in schizophrenic patients.

235. Pfizer's unlawful marketing scheme extended to its drug Geodon. Geodon's competition was other psychiatric drugs, including the lucrative drugs Rispderal and Seroquel.

236. Geodon is a dangerous drug and indeed a drug of last resort because of the serious adverse side effects it can cause. In patients with heart conditions or a slow heart beat known as a QT prolongation, Geodon can create serious heart beat irregularities which are potentially fatal. The interactions of Geodon with other drugs can enhance these adverse events.

237. Defendant engaged in a pattern of reckless off label marketing of Geodon for non-indicated purposes. In combination with kickbacks, Defendant's marketing schemes were designed to unlawfully expand the market for Geodon at significant cost to federal and State health care systems. By engaging in these schemes, Defendant downplayed the risks of its drug which it marketed off-label and continued marketing even after the prescriptions were known to be unnecessary and fraudulent.

238. Pfizer's reckless marketing scheme for Geodon had the impact of encouraging the prescription of drugs in the Townstreet practice in Columbus, Ohio. This clinic was a polyprescribing setting (prescribing many drugs per patient for profit without proper

medical diagnosis), without any legitimate study validating the safety and efficacy of Geodon in combination with prescriptions of many other unrelated drugs. Specialists receiving referrals from this clinic found patients receiving many prescriptions unrelated to any medical diagnosis the patient knew about.

239. In 2003, Relator learned that Pfizer's unlawful marketing practices encompassed Geodon when a Pfizer representative who marketed Geodon provided him with information that there were unlawful practices involving large numbers of Geodon prescriptions being written by the doctors at the Townstreet practice in Columbus, Ohio. Not only is Geodon a drug with dangerous side effects, it should only be prescribed in conjunction with adequate psychiatric oversight of the patients.

240. In March 2004, Relator made a specific report involving Geodon and the Townstreet Family Practice to Andrew Powell, Pfizer's Regional Human Resources Director. Relator told Mr. Powell that the practices involving Geodon were not only unlawful, but that they placed patients at risk.

241. On March 29, 2004, Relator DeMott emailed Human Resource Manager Andrew Powell a message pointing out that the Townstreet Clinic was involved in very extensive and potentially dangerous off-label uses of Geodon, instigated by a physician who had since lost his license. Relator reported that because of continued marketing, illegal payments, and a formulary promoting Pfizer drugs at this Clinic, the high rate of Geodon use continued unabated.

H. Pfizer Retaliation and Relator's Reports to the Government

242. When Relator's internal efforts to report illegal marketing activities, including meeting with Pfizer's national compliance office in New York, proved largely unsuccessful, on

February 11, 2005, Relator contacted the FDA and the FBI regarding Pfizer's marketing activities as set forth above. Follow-up calls and meetings continued in the spring of 2005 and thereafter, continuing into 2009.

243. As a result of Relator's reporting of, and opposition to, illegal Relpax marketing schemes and other Pfizer illegal activities, on November 2, 2004, the day he was to return to work after a long vacation, Pfizer placed Relator on administrative leave. Pfizer prohibited Relator from returning to sales work at the company.

244. As a result of Relator's investigation and reports of fraud proscribed by the False Claims Act (FCA), he suffered retaliation by the Defendant and was terminated effective April 15, 2005.

I. Pfizer's False Certification of Compliance with Applicable Health Care Agreements, Statutes, Regulations and Procedures

245. Defendant Pfizer submitted claims to the government in violation of the False Claims Act by falsely certifying that it was in compliance with all applicable health care agreements, laws, procedures, and regulations as required by its Corporate Integrity Agreement with the U.S. Department of Health and Human Services. In addition, Pfizer breached the Corporate Integrity Agreement by failing to provide a non-retaliatory environment for Relator and others who reported violations of federal health program requirements through Pfizer's Disclosure Program.

246. Defendant Pfizer understood that strict adherence and compliance with all statutes, regulations, guidelines applicable to all federal health care programs and with its own Policies and Procedures, including the duty to report any non-compliance, was a prerequisite to participation in the Medicare and Medicaid Programs and a basis for exclusion from these programs under the terms of the Corporate Integrity Agreement.

247. Upon information and belief, when seeking reimbursement for its services from Medicare and Medicaid, Defendant Pfizer certified to the government its compliance with all federal and state regulations, including the False Claims Act, Anti-Kickback Statute, and Stark Law. By certifying full compliance with such regulations when Defendant Pfizer knew or should have known that it was not in compliance, Pfizer submitted false claims to the government in violation of the False Claims Act.

VI. CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
(False Claims Act: Presentation of False Claims)
(U.S.C. § 3729(a)(1))

248. The allegations of the preceding paragraphs are realleged as if fully set forth.

249. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein, Defendant Pfizer has knowingly presented or caused to be presented to officers or employees of the United States Government and the governments of the Individual States, false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1).

SECOND CAUSE OF ACTION
(False Claims Act: Making or Using False Record or Statement to Cause Claim to be Paid)
(U.S.C. § 3729(a)(2))

250. The allegations of the preceding paragraphs are realleged as if fully set forth.

251. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged, Defendant Pfizer knowingly made, used, or caused to be made or used false or fraudulent records or statements, to get false or fraudulent claims paid or approved by the Government and the Individual States in violation of 31 U.S.C. § 3729(a)(2).

THIRD CAUSE OF ACTION
(False Claims Act: Making or Using False Record or Statement to Avoid an Obligation to Refund)
(U.S.C. § 3729(a)(7))

252. The allegations of the preceding paragraphs are realleged as if fully set forth.

253. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged, Defendant Pfizer knowingly made, used, or caused to be made or used, false or fraudulent records or statements to conceal, avoid or decrease an obligation to pay or transmit money or property to the United States of America.

FOURTH CAUSE OF ACTION
(False Claims Act Retaliation Violation and Civil Rights Retaliation)
U.S.C. § 3730(h) and 42 U.S.C. § 1985)

254. The allegations of the preceding paragraphs and those that follow in subsequent Counts are realleged as if fully set forth.

255. Defendant has a duty under the False Claims Act, 31 U.S.C. § 3730(h), and under 42 U.S.C. § 1985, to refrain from taking retaliatory actions against employees who take lawful actions in furtherance of a False Claims Act action, including investigation for, testimony for, or assistance in an action filed under this section and federal investigations.

256. Relator took lawful actions in furtherance of a False Claims Act action and the DOJ and FDA investigation of Pfizer, including investigation for, testimony for, or assistance in an action filed under this section and, as such, engaged in protected activity under the False Claims Act and other laws.

257. While employed by Defendant, and after his employment was illegally terminated, Relator repeatedly questioned, investigated, and reported internally and subsequently to appropriate Government officials on Defendant's improper practices and billing in

connection with federal and state-funded health care programs in furtherance of a False Claims Act action.

258. Defendant has without good cause harassed, intimidated, and otherwise created a hostile work environment for Relator in retaliation for his objections to, and reporting of, Defendant's wrongdoing. Defendant knew or should have known that Relator's activities investigating and opposing its unlawful conduct, including his investigation for, testimony for, or assistance in an action filed under this section, were in connection with this False Claims Act action.

259. Immediately prior to and during his January 2008 deposition in an age discrimination case, Pfizer's retaliation against Relator continued. Pfizer's attorney objected to and interfered with Relator providing truthful testimony regarding Pfizer's unlawful marketing, False Claims Act violations described herein, and retaliation against himself and other Pfizer sales representatives who objected to and reported violations of law and of Pfizer's Corporate Integrity Agreement. Pfizer's Counsel threatened Relator's Counsel with financial penalties if Relator testified in a fully responsive manner to the questions about Pfizer's drug marketing practices, even though Relator had been subpoened. The discrimination case was settled immediately after Relator's deposition testimony was concluded.

260. Defendant retaliated against Relator for his lawful actions taken in furtherance of a False Claims Act action and the FDA-DOJ investigation of Pfizer, including, but not limited to, his investigation and assistance in an action alleging Defendant's violations of the False Claims Act and Relator's efforts to prevent further False Claims Act violations by

Defendant. Relator reported, at various times, all of the above violations of law recited in this Complaint to his superiors at Pfizer and to the FDA prior to filing this action.

261. The actions of Defendant damaged and continue to damage Relator in violation of 31 U.S.C. § 3730(h) and 42 U.S.C. § 1985, in an amount to be determined at trial.

262. Defendant's misconduct and illegal treatment of Relator and those it derogatorily considers "whistleblowers" has the effect of stifling reports of off-label marketing, kickback schemes, and violations of Medicaid best-price requirements. This treatment effectively warned other Pfizer employees that they should not engage in honest and open reporting of Defendant's conduct.

263. Pursuant to 31 U.S.C. § 3730(h) and 42 U.S.C. § 1985, Relator is entitled to litigation costs and reasonable attorneys' fees incurred in the vindication of his reputation and the pursuit of his retaliation claims.

FIFTH CAUSE OF ACTION
(Ohio State Public Policy Tort: Greeley Claim)

264. The allegations of the preceding paragraphs are realleged as if fully set forth.

265. At all times pertinent hereto, Pfizer was a foreign corporation doing business in, and deriving substantial revenue from, business in the state of Ohio.

266. At all times pertinent hereto, Relator was a senior pharmaceutical sales consultant and assigned to the territory including Columbus, Ohio.

267. At all times pertinent hereto, Relator was acting in his scope and capacity of employment with Defendant.

268. It is the public policy of the state of Ohio that illegal conduct, including theft by deception and fraud, fraud against the Medicaid, Medicare, and public health care systems and publicly-funded health programs and insurance, shall not be tolerated.

269. It is further the public policy of Ohio that witnesses to criminal activity shall not be intimidated or coerced, as evidenced by R.C. 2905.11, R.C. 2905.12, R.C. 2921.02 and R.C. 2921.03, among other statutes and regulations, such that the policy against theft through fraud may be furthered by the law enforcement and judicial systems. It is further the public policy of Ohio that no one shall obstruct justice as evidenced by R.C. 2921.32(A)(4) and (A)(5) nor obstruct official business as evidenced by R.C. 2923.31.

270. It is further the public policy of Ohio, as found in the constitutional, statutory and regulatory provisions, that persons shall be free to express themselves on matters of public interest.

271. Relator reasonably believed that Pfizer defrauded Medicare, Medicaid, and private insurers when it illegally marketed drugs as provided herein.

272. Relator repeatedly protested this action to Pfizer management and compliance officers, but received little or no response.

273. The harassment initiated and continued by Pfizer management continued until at least April 2005, when Relator was terminated. Defendant's actions violated Ohio's public policy as set forth above.

274. Harassment and adverse employment actions taken against one opposing such activities jeopardize the public policies identified above and elsewhere in this Complaint.

275. As a direct and proximate result of the retaliation against him for opposing the unlawful conduct, Relator has suffered extreme emotional and mental anguish, lost self-esteem, humiliation, physical illness, lost income and benefits, and will suffer further such injuries and losses in the future. As a direct and proximate result of the retaliation, Relator has suffered permanent loss of earning capacity.

SIXTH CAUSE OF ACTION
(Public Policy Tort Involving Ohio Department of Human Services (Medicaid))

276. The allegations of the preceding paragraphs are realleged as if fully set forth.

277. It is the public policy of the state of Ohio that illegal conduct, including theft by deception and fraud upon investors, shall not be tolerated. It is further the public policy of Ohio that witnesses to criminal activity shall not be intimidated or coerced, as evidenced by R.C. 2905.11, R.C. 2905.12, R.C. 2921.02 and R.C. 2921.03, among other statutes and regulations, such that the policy against theft through fraud may be furthered by the law enforcement and judicial systems. It is further the public policy of Ohio that no one shall obstruct justice as evidenced by R.C. 2921.32 (A)(4) and (A)(5), nor obstruct official business as evidenced by R.C. 2923.31. It is further the public policy of Ohio, as found in the constitutional, statutory and regulatory provisions, that persons shall be free to express themselves on matters of public interest.

278. From at least 1997 and continuing today, Ohio, by and through its Medicaid assistance to low income and disabled persons, has paid for Defendant's pharmaceutical products.

279. Relator protested Defendant's marketing techniques as described herein, but received little if any response.

280. Pfizer and its agents and employees repeatedly harassed Relator.

281. Harassment and adverse employment actions taken against one opposing such activities jeopardize the public policies identified above.

282. As a direct and proximate result of the retaliation against him for opposing the conduct, Relator has suffered extreme emotional and mental anguish, lost self-esteem, humiliation, physical illness, lost income and benefits, and will suffer further such injuries and losses

in the future. As a direct and proximate result of the retaliation, Relator has suffered permanent loss of earning capacity.

SEVENTH CAUSE OF ACTION
(Public Policy Tort: Fraud and Deception to Shareholders)

283. The allegations of the preceding paragraphs are realleged as if fully set forth.

284. It is the public policy of the state of Ohio that theft offenses, including theft by deception and fraud upon investors, shall not be tolerated.

285. It is further the public policy of Ohio that witnesses to criminal activity shall not be intimidated or coerced, as evidenced by R.C. 2905.11, R.C. 2905.12, R.C. 2921.02 and R.C. 2921.03, among other statutes and regulations, such that the policy against theft through fraud may be furthered by the law enforcement and judicial systems. It is further the public policy of Ohio that no one shall obstruct justice as evidenced by R.C. 2921.32 (A)(4) and (A)(5), nor obstruct official business as evidenced by R.C. 2923.31. It is further the public policy of Ohio, as found in the constitutional, statutory and regulatory provisions, that persons shall be free to express themselves on matters of public interest.

286. Relator continued to oppose Pfizer's illegal activity as described herein, both individually and in team meetings but as he did so, Pfizer and various of its employees became more and more hostile to Relator's attempts to report and correct Pfizer's compliance violations.

287. As a direct and proximate result of the retaliation against him for opposing the conduct, Relator has suffered extreme emotional and mental anguish, lost self-esteem, humiliation, physical illness, lost income and benefits, and will suffer further such injuries and losses in the future. As a direct and proximate result of the retaliation, Relator has suffered permanent loss of earning capacity.

EIGHTH CAUSE OF ACTION
(Violation of Ohio R.C. 4113.52, Ohio Whistleblower Act)

288. The allegations of the preceding paragraphs are realleged as if fully set forth.

289. Relator complied with the notice requirements of Ohio R.C. 4113.52 *et seq.* in reporting what he reasonably believed to be criminal activity constituting felonies.

290. Defendant failed to comply with the requirements of the statute that provides for investigation and written report to the employee within 24 hours of the report.

291. Defendant retaliated against Relator for having made the reports.

292. As a direct and proximate result, Relator has suffered extreme emotional and mental anguish, lost self-esteem, humiliation, physical illness, lost income and benefits, and will suffer further such injuries and losses in the future. As a direct and proximate result of the retaliation, Relator has suffered permanent loss of earning capacity.

NINTH CAUSE OF ACTION
(California False Claims Act)
(Cal. Gov't Code § 12651, *et seq.*)

293. The allegations of the preceding paragraphs are realleged as if fully set forth.

294. This is a claim for treble damages and civil penalties under the California False Claims Act. Cal. Gov't Code § 12651, *et seq.*

295. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the California Medicaid Program (i.e., Medi-Cal) false or fraudulent claims for the improper payment or approval of prescriptions for Celebrex, Bextra, Lyrica, Relpax, Depo-Provera, and Geodon and used false or fraudulent records to accomplish this purpose.

296. The California Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

297. By reason of these payments, the California Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TENTH CAUSE OF ACTION
(Delaware False Claims Act)
(Del. Code Ann. tit. 6, § 1201, *et seq.*)

298. The allegations of the preceding paragraphs are realleged as if fully set forth.

299. This is a claim for treble damages and civil penalties under the Delaware False Claims Act. Del Code Ann. tit. 6, § 1201, *et seq.*

300. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Delaware Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Celebrex, Bextra, Relpax, Depo-Provera, Lyrica, and Geodon and used false or fraudulent records to accomplish this purpose.

301. The Delaware Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

302. By reason of these payments, the Delaware Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

ELEVENTH CAUSE OF ACTION
(Florida False Claims Act)
(Fla. Stat. Ann. § 68.081, *et seq.*)

303. The allegations of the preceding paragraphs are realleged as if fully set forth.

304. This is a claim for treble damages and civil penalties under the Florida False Claims Act. Fla. Stat. Ann. § 68.081, *et seq*.

305. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Florida Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Celebrex, Bextra, Relpax, Depo-Provera, Lyrica, and Geodon and used false or fraudulent records to accomplish this purpose.

306. The Florida Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

307. By reason of these payments, the Florida Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TWELFTH CAUSE OF ACTION
(Georgia's False Medicaid Claims Act)
(Ga. Code Ann. § 49-4-168 (2007))

308. The allegations of the preceding paragraphs are realleged as if fully set forth.

309. This is a claim for treble damages and civil penalties under the False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 (2007).

310. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Georgia Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Celebrex, Bextra, Relpax, Depo-Provera, Lyrica, and Geodon and used false or fraudulent records to accomplish this purpose.

311. The Georgia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

312. By reason of these payments, the Georgia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

THIRTEENTH CAUSE OF ACTION
(Hawaii False Claims Act)
(Haw. Rev. Stat. § 661-22, *et seq.*)

313. The allegations of the preceding paragraphs are realleged as if fully set forth.

314. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act. Haw. Rev. Stat. § 661-22, *et seq*.

315. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Hawaii Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Celebrex, Bextra, Relpax, Depo-Provera, Lyrica, and Geodon and used false or fraudulent records to accomplish this purpose.

316. The Hawaii Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

317. By reason of these payments, the Hawaii Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

FOURTEENTH CAUSE OF ACTION
(Illinois Whistleblower Reward and Protection Act)
(740 Ill. Comp. Stat. 175/1, *et seq.*)

318. The allegations of the preceding paragraphs are realleged as if fully set forth.

319. This is a claim for treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act. 740 III. Comp. Stat. 175/1, *et seq*.

320. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the

Illinois Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Celebrex, Bextra, Relpax, Depo-Provera, Lyrica, and Geodon and used false or fraudulent records to accomplish this purpose.

321. The Illinois Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

322. By reason of these payments, the Illinois Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

FIFTEENTH CAUSE OF ACTION
(Indiana False Claims and Whistleblower Protection)
(Burns Ind. Code Ann. § 5-11-5.5-1 *et seq.*)

323. The allegations of the preceding paragraphs are realleged as if fully set forth.

324. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Law. Burns Ind. Code Ann. § 5-11-5.5-1 *et seq*.

325. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Indiana Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Celebrex, Bextra, Relpax, Depo-Provera, Lyrica, and Geodon and used false or fraudulent records to accomplish this purpose.

326. The Indiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

327. By reason of these payments, the Indiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

SIXTEENTH CAUSE OF ACTION
(Louisiana Medical Assistance Programs Integrity Law)
(La. Rev. Stat. Ann. § 46:439.1, *et seq.*)

328. The allegations of the preceding paragraphs are realleged as if fully set forth.

329. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law. La. Rev. Stat. Ann. § 46:439.1, *et seq.*

330. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Louisiana Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Celebrex, Bextra, Relpax, Depo-Provera, Lyrica, and Geodon and used false or fraudulent records to accomplish this purpose.

331. The Louisiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

332. By reason of these payments, the Louisiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

SEVENTEENTH CAUSE OF ACTION
(Massachusetts False Claims Act)
(Mass. Ann. Laws ch. 12, § 5(A)-(0))

333. The allegations of the preceding paragraphs are realleged as if fully set forth.

334. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Act. Mass. Ann. Laws ch. 12, § 5(A)-(0).

335. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Massachusetts Medicaid Program false or fraudulent claims for the improper payment or

approval of prescriptions for Celebrex, Bextra, Relpax, Depo-Provera, Lyrica, and Geodon and used false or fraudulent records to accomplish this purpose.

336. The Massachusetts Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

337. By reason of these payments, the Massachusetts Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

EIGHTEENTH CAUSE OF ACTION
(Michigan Medicaid False Claim Act)
(Michigan Compiled Law §400.601 *et seq.*)

338. The allegations of the preceding paragraphs are realleged as if fully set forth.

339. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claim Act. MCL §400.601 *et seq.*

340. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Michigan Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Celebrex, Bextra, Relpax, Depo-Provera, Lyrica, and Geodon and used false or fraudulent records to accomplish this purpose.

341. The Michigan Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

342. By reason of these payments, the Michigan Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

NINETEENTH CAUSE OF ACTION
(Montana False Claims Act)
(Mont. Code Anno. §17-8-401 *et seq.*)

343. The allegations of the preceding paragraphs are realleged as if fully set forth.

344. This is a claim for treble damages and civil penalties under the Montana False Claims Act. Mont. Code Anno. § 17-8-401 *et seq.*

345. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Montana Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Celebrex, Bextra, Relpax, Depo-Provera, Lyrica, and Geodon and used false or fraudulent records to accomplish this purpose.

346. The Montana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

347. By reason of these payments, the Montana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TWENTIETH CAUSE OF ACTION
(Nevada False Claims Act)
(Nev. Rev. Stat. § 357.010, *et seq.*)

348. The allegations of the preceding paragraphs are realleged as if fully set forth.

349. This is a claim for treble damages and civil penalties under the Nevada False Claims Act. Nev. Rev. Stat. § 357.010, *et seq.*

350. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Nevada Medicaid Program false or fraudulent claims for the improper payment or

approval of prescriptions for Celebrex, Bextra, Relpax, Depo-Provera, Lyrica, and Geodon and used false or fraudulent records to accomplish this purpose.

351. The Nevada Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

352. By reason of these payments, the Nevada Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TWENTY-FIRST CAUSE OF ACTION
(New Hampshire Medicaid Fraud and False Claims),
(N.H. Rev. Stat. Ann. § 167:61, *et seq.*)

353. The allegations of the preceding paragraphs are realleged as if fully set forth.

354. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims Law. N.H. Rev. Stat. Ann. § 167:61, *et seq*.

355. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the New Hampshire Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Celebrex, Bextra, Relpax, Depo-Provera, Lyrica, and Geodon and used false or fraudulent records to accomplish this purpose.

356. The New Hampshire Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

357. By reason of these payments, the New Hampshire Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TWENTY-SECOND CAUSE OF ACTION
(New Mexico Medicaid False Claims Act)
(N.M. Stat. Ann. § 27-14-1, *et seq.*)

358. The allegations of the preceding paragraphs are realleged as if fully set forth.

359. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act. N.M. Stat. Ann. § 27-14-1, *et seq*.

360. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the New Mexico Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Celebrex, Bextra, Relpax, Depo-Provera, Lyrica, Geodon and used false or fraudulent records to accomplish this purpose.

361. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

362. By reason of these payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TWENTY-THIRD CAUSE OF ACTION
(New York False Claims Act)
(N.Y CLS St. Fin. § 186 *et seq.*)

363. The allegations of the preceding paragraphs are realleged as if fully set forth.

364. This is a claim for treble damages and civil penalties under the New York False Claims Act. N.Y CLS St. Fin. § 186 *et seq*.

365. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the New York Medicaid Program false or fraudulent claims for the improper payment or

approval of prescriptions for off-label uses and used false or fraudulent records to accomplish this purpose.

366. The New York Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

367. By reason of these payments, the New York Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TWENTY-FOURTH CAUSE OF ACTION
(New Jersey False Claims Act)
(N.J. Stat. § 2A:32C-1 *et seq.*)

368. The allegations of the preceding paragraphs are re-alleged as if fully set forth.

369. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act. N.J. Stat. § 2A:32C-1 *et seq*.

370. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the New Jersey Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses and used false or fraudulent records to accomplish this purpose.

371. The New Jersey Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

372. By reason of these payments, the New Jersey Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TWENTY-FIFTH CAUSE OF ACTION
(Oklahoma Medicaid False Claims Act)
(63 Okl. St. § 5053 *et seq.*)

373. The allegations of the preceding paragraphs are realleged as if fully set forth.

374. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, 63 Okl. St. § 5053 *et seq*.

375. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Oklahoma Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Celebrex, Bextra, Relpax, Depo-Provera, Lyrica, Geodon and used false or fraudulent records to accomplish this purpose.

376. The Oklahoma Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

377. By reason of these payments, the Oklahoma Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TWENTY-SIXTH CAUSE OF ACTION
(Rhode Island False Claims Act)
(R.I. Gen. Laws § 9-1.1-1 *et seq.*)

378. The allegations of the preceding paragraphs are realleged as if fully set forth.

379. This is a claim for treble damages and civil penalties under the Rhode Island False Claims Act. R.I. Gen. Laws § 9-1.1-1 *et seq*.

380. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Rhode Island Medicaid Program false or fraudulent claims for the improper payment or

approval of prescriptions for Celebrex, Bextra, Relpax, Depo-Provera, Lyrica, Geodon and used false or fraudulent records to accomplish this purpose.

381. The Rhode Island Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

382. By reason of these payments, the Rhode Island Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TWENTY-SEVENTH CAUSE OF ACTION
(Tennessee Medicaid False Claims Act)
(Tenn. Code Ann. § 71-5-181, *et seq.*)

383. The allegations of the preceding paragraphs are realleged as if fully set forth.

384. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, and the Tennessee False Claims Act. Tenn. Code Ann. § 71-5-181 *et seq.*; Tenn. Code Ann. § 4-18-101, *et seq*.

385. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Tennessee Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Celebrex, Bextra, Relpax, Depo-Provera, Lyrica, and Bextra and used false or fraudulent records to accomplish this purpose.

386. The Tennessee Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

387. By reason of these payments, the Tennessee Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TWENTY-EIGHTH CAUSE OF ACTION
(Texas Medicaid Fraud Prevention Act)
(Tex. Hum. Res. Code Ann. § 36.001, *et seq.*)

388. The allegations of the preceding paragraphs are realleged as if fully set forth.

389. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Act. Tex. Hum. Res. Code Ann. § 36.001, *et seq.*

390. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Texas Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Celebrex, Bextra, Relpax, Depo-Provera, Lyrica, and Geodon and used false or fraudulent records to accomplish this purpose.

391. The Texas Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

392. By reason of these payments, the Texas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

TWENTY-NINTH CAUSE OF ACTION
(Virginia Fraud Against Taxpayers Act)
(Va. Code Ann. § 8.01-216, *et seq.*)

393. The allegations of the preceding paragraphs are realleged as if fully set forth.

394. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act. Va. Code Ann. §8.01-216, *et seq.*

395. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Virginia Medicaid Program false or fraudulent claims for the improper payment or

approval of prescriptions for Celebrex, Bextra, Relpax, Depo-Provera, Lyrica, and Geodon and used false or fraudulent records to accomplish this purpose.

396. The Virginia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

397. By reason of these payments, the Virginia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

THIRTIETH CAUSE OF ACTION
(Wisconsin False Claims Act)
(Wis. Stat. § 20.931 *et seq.*)

398. The allegations of the preceding paragraphs are realleged as if fully set forth.

399. This is a claim for treble damages and civil penalties under the Wisconsin False Claims Act. Wis. Stat. § 20.931 *et seq*.

400. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the Wisconsin Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for Celebrex, Bextra, Relpax, Depo-Provera, Lyrica, and Geodon and used false or fraudulent records to accomplish this purpose.

401. The Wisconsin Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

402. By reason of these payments, the Wisconsin Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

THIRTY-FIRST CAUSE OF ACTION
(District of Columbia False Claims Act)
(D.C. Code § 2-308.03, *et seq.*)

403. The allegations of the preceding paragraphs are realleged as if fully set forth.

404. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act. D.C. Code § 2-308.03, *et seq.*

405. By virtue of the kickbacks, off-label and false marketing, and submissions of non-reimbursable claims described above, Defendant knowingly caused to be presented to the District of Columbia Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses of Celebrex, Bextra, Relpax, Depo-Provera, Lyrica and Geodon and used false or fraudulent records to accomplish this purpose, and conspired with each other to effectuate this plan.

406. The District of Columbia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendant, paid for claims that otherwise would not have been allowed.

407. By reason of these payments, the District of Columbia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

WHEREFORE, Relator Glenn DeMott requests that judgment be entered against the Defendant, ordering that:

a. Defendant cease and desist from violating the False Claims Act, 31 U.S.C. § 3729, *et seq.*;

b. Defendant pay not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729, plus three times the amount of damages the United States has sustained because of the Defendant's actions;

c. Relator be awarded the maximum "relator's share" allowed pursuant to 31 U.S.C. § 3730(d) and similar provisions of the state false claims acts;

d. Relator be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d) and similar provisions of the state false claims acts;

e. Relator be provided with injunctive or equitable relief, as may be appropriate, to prevent further harm to themselves and to prevent the harm to others and the public caused by Defendant's retaliation against whistleblowers;

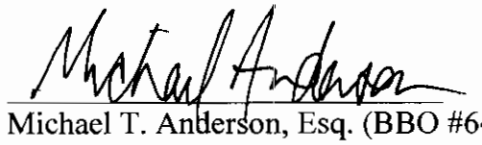
f. Relator be awarded all litigation costs, expert fees, and reasonable attorneys' fees incurred as provided pursuant to 31 U.S.C. § 3730(h) and other applicable law;

g. Defendant be enjoined from concealing, removing, encumbering or disposing of assets which may be required to pay the civil monetary penalties imposed by the Court;

h. Defendant disgorge all sums by which it has been enriched unjustly by its wrongful conduct; and

i. The United States, the Individual States, and Relator recover such other relief as the Court deems just and proper.

Respectfully Submitted,



Michael T. Anderson, Esq. (BBO #645533)
MURPHY ANDERSON PLLC
111 Devonshire St. 5th Fl.
Boston, MA 02109
Phone: (617) 227-5720
Fax: (617) 227-5767
manderson@murphypllc.com

Ann Lugbill, Esq. (Ohio Bar 0023632)
MURPHY ANDERSON PLLC
2406 Auburn Avenue
Cincinnati, OH 45219
Phone: (513) 784-1280
Fax: (513) 784-1449
alugbill@murphypllc.com

Mark Hanna, Esq.
MURPHY ANDERSON PLLC
1701 K Street, NW, Suite 210
Washington, DC 20006
Phone: (202) 223-1057
Fax: (202) 223-8651
mhanna@murphypllc.com

John Kairis, Esq.
GRANT & EISENHOFER, PA
Chase Manhattan Centre
1201 North Market Street
Wilmington, DE 19801
Phone: (302) 622-7000
Fax: (302) 622-7100
jkairis@gelaw.com

Reuben Guttman, Esq.
Traci Buschner, Esq.
GRANT & EISENHOFER, PA
1920 L Street, NW, Suite 400
Washington, DC 20036
Phone: (202) 386-9500
Fax: (202) 386-9505
rguttman@gelaw.com
tbuschner@gelaw.com

Attorneys for Relator

CERTIFICATE OF SERVICE

I hereby certify that the foregoing Amended Complaint and Jury Demand was served this 15th day of April 2009, upon the following as indicated below.

Ann Lugbill, Esq. (Ohio Bar 0023632)
MURPHY ANDERSON PLLC
2406 Auburn Avenue
Cincinnati, OH 45219
Phone: (513) 784-1280
Fax: (513) 784-1449
alugbill@murphypllc.com

Via Regular U.S. Mail

Sanjay M. Bhambhani
U.S. Department of Justice
P.O. Box 261
Ben Franklin Station
Washington, DC 20044
(202) 305-0546

Colin M. Huntley
U.S. Department of Justice
P.O. Box 261
Ben Franklin Station
Washington, DC 20044
(202) 353-8190

Sara Miron Bloom
Chief of Affirmative Litigation
District of Massachusetts
United States Attorney's Office
1 Courthouse Way
Boston, MA 02210
(617) 748-3100

John Kairis, Esq.
Grant & Eisenhofer, PA
Chase Manhattan Centre
1201 North Market Street
Wilmington, DE 19801
(302) 622-7000

Via Regular U.S. Mail

California Attorney General
Attn: Carlotta R. Hivoral
Bureau of Medi-Cal Fraud and Elder Abuse
1455 Frazee Road, Suite 315
San Diego, CA 92108-4304

Joseph R. Biden, III
Delaware Attorney General
Carvel State Office Building
820 N. French Street
Wilmington, DE 19801

Bill McCollum
Florida Attorney General
The Capitol PL-01
Tallahassee, FL 32399-1050

Alex Sink, CFO
Florida Department of Financial Services
Division of Legal Services
c/o Pete Dunbar
200 East Gaines Street
Tallahassee, FL 32399-0033

Mark J. Bennett
Hawaii Attorney General
425 Queen Street
Honolulu, HI 96813

Lisa Madigan
Illinois Attorney General
100 West Randolph Street
Chicago, IL 60601

James D. Caldwell
Louisiana Attorney General
Livingston Building, P.O. Box 94005
1885 N. Third Street, 6th Floor
Baton Rouge, LA 70802

Martha Coakley
Massachusetts Attorney General
McCormack Building
One Ashburton Place
Boston, MA 02108

Catherine Cortez Masto
Nevada Attorney General
Nevada Department of Justice
100 North Carson Street
Carson City, NV 89701

Kelly A. Ayotte
New Hampshire Attorney General
33 Capitol Street
Concord, NH 03301

Gary King
New Mexico Attorney General
408 Galisteo Street
Villagra Building
Santa Fe, NM 87501

Tennessee Attorney General
Attn: Peter Coughlan
Antitrust Division
P.O. Box 20207
Nashville, TN 37202

Texas Attorney General
Attn: Noelle C. Letteri
Antitrust and Civil Medicaid Fraud
Division
P.O. Box 12548
Austin, TX 78711

Virginia Attorney General
Attn: Guy W. Horsley,
Qui Tam Coordinator
900 East Main Street
Richmond, VA 23219

District of Columbia Attorney General
Attn: Jane Drummey
Civil Enforcement Section, Public
Advocacy Division
441 Fourth Street, Suite 450 North
Washington, DC 20001

Via Certified Mail w/return receipt

Thurbert E. Baker
Georgia Attorney General
40 Capitol Square, SW
Atlanta, GA 30334

Steve Carter
Indiana Attorney General
Indiana Government Center South
302 W. Washington St.
Indianapolis, IN 46204

Dave Thomas
Inspector General of Indiana
150 West Market Street, Room 414
Indianapolis, IN 46204

Mike Cox
Michigan Attorney General
G. Mennen Williams Building,
7th Floor
525 W. Ottawa St.
Lansing, MI 48909

Mike McGrath
Montana Attorney General
Justice Building
215 N. Sanders
Helena, MT 59620-1401

Anne Milgram
New Jersey Attorney General
Richard J. Hughes Justice Complex
25 Market Street
Trenton, NJ 08625-0080

Andrew M. Cuomo
New York Attorney General
The Capitol
Albany, NY 12224-0341

W.A. Drew Edmonson
Oklahoma Attorney General
313 NE 21st Street
Oklahoma City, OK 73105

Patrick C. Lynch
Rhode Island Attorney General
150 South Main Street
Providence, RI 02903

J.B. Van Hollen
Wisconsin Attorney General
Risser Justice Center
17 West Main Street
Madison, WI 53707-7857